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No. 98-1768

Supreme Court, U.S.
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In the Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

JOINT APPENDIX

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RELEVANT DOCKET ENTRIES

August 8, 1994	Order of the Judicial Panel on Multidistrict Litigation entered transferring individual actions to Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings
Oct. 25, 1994	Motion to dismiss for failure to state a claim filed by AcroMed Corporation
Jan. 23, 1995	Motion to dismiss for failure to state a claim and for lack of subject matter and personal jurisdiction filed by Arthur Steffee and Edward Wagner
Feb. 13, 1995	Motions to dismiss for failure to state a claim filed by AcroMed Corporation
March 2, 1995	Memorandum and Pretrial Order No. 12 entered granting motions for partial judgment on the pleadings filed by AcroMed Corporation, Arthur Steffee and Edward Wagner
April 17, 1995	Motion for summary judgment or partial summary judgment on the grounds of preemption or deference to agency expertise filed by AcroMed Corporation
Oct. 31, 1996	Motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr* filed by AcroMed Corporation
Nov. 1, 1996	Joinder by Buckman Company in AcroMed's motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr*

Dec. 2. 1996	Motion to dismiss amended omni complaint for failure to state a claim upon which relief may be granted filed by Buckman Company
March 28, 1997	Memorandum and Pretrial Order No. 845 entered granting in part motion to reaffirm Pretrial Order No. 12 in light of *Medtronic, Inc.* v. *Lohr*
April 7, 1997	Motion for certification of immediate interlocutory appeal under 28 U.S.C. § 1292(b) of issues decided in Pretrial Order No. 845 filed by Plaintiffs' Legal Committee
May 12, 1997	Pretrial Order No. 900 entered granting Buckman Company's motion to dismiss amended omni complaint for failure to state a claim upon which relief may be granted
Sept. 12, 1997	Pretrial order no. 1067 entered directing entry of final judgment under Fed. R. Civ. P. 54(b) in favor of Buckman Company on plaintiffs' fraud-on-the-FDA claims in the amended omni complaints and dismissing Buckman Company from litigation
Nov. 17, 1998	Opinion and judgment by the U.S. Court of Appeals for the Third Circuit entered reversing judgment of district court and remanding for further proceedings
June 29, 2000	Order of the Supreme Court of the United States entered granting Buckman Company's petition for a writ of certiorari

RELEVANT DOCKET ENTRIES NOT INCLUDED

The following opinions, decisions, judgments, and orders have been omitted in printing this joint appendix because they appear at the pages indicated in the appendix to the Petition for a Writ of Certiorari:

Memorandum Opinion and Pretrial Order No. 12 of the United States District Court for the Eastern District of Pennsylvania, dated March 2, 1995 ..... 46a

Memorandum Opinion and Pretrial Order No. 845 of the United States District Court for the Eastern District of Pennsylvania, dated March 28, 1997 ..... 33a

Pretrial Order No. 900 of the United States District Court for the Eastern District of Pennsylvania, dated May 12, 1997 ..... 45a

Pretrial Order No. 1067, Final Judgment Order Pursuant To Fed. R. Civ. P. 54(b), of the United States District Court for the Eastern District of Pennsylvania, dated Sept. 12, 1997 ..... 54a

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IN THE SUPREME COURT OF THE UNITED STATES

Buckman Company, Petitioner
v.
Plaintiffs' Legal Committee, Respondent.
No. 98-1768

June 29, 2000

Motion of Medical Device Manufacturers Association for leave to file a brief as amicus curiae granted. Motion of Danek Medical, Inc., for leave to file a brief as amicus curiae granted. Motion of Product Liability Advisory Council, Inc., for leave to file a brief as amicus curiae granted. Motion of Pharmaceutical Research and Manufacturers of America for leave to file a brief as amicus curiae granted. Petition for writ of certiorari to the United States Court of Appeals for the Third Circuit granted limited to the following question: Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

IN THE UNITED STATES DISTRICT COURT
JUDICIAL DISTRICT OF ALASKA

Donald G. Patterson, and Linda A. Patterson, Plaintiff,
v.
AcroMed Corporation, Charter No. 614043; AcroMed Corp. (Now AcroMed Corporation, Charter No. 614043); AcroMed Corporation, Charter No. 816942; AcroMed Inc., Charter No. 811415); AcroMed Incorporated, Charter No. 816943; AcroMed Holding Corporation, Charter No. 811416); AcroMed Corporation (now AcroMed Holding Corporation, Charter No. 811416); Horizon Orthopedic, Inc., f/k/a Steffee Orthopedic, Inc., f/k/a Arthur D. Steffee, MD., Inc.; Arthur D. Steffee; William C. Carson; Isola Implants, Inc.; Behrooz Akbarnia; Marc Asher; Robert Biscup; John Brantigan; Mark Brown; Samuel Chewning; Sanford Davne; Robert Gaines; Brad Hall; Charles Heinig; Louis Keppler; Mark Lorenz; Paul C. McAfee; Donald Myers; Theodore Wagner; James Weinstein; Michael Zindrick; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; American Association of Neurological Surgeons; Buckman Company, Inc.; Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; Danek Medical, Inc.; Sofamore, Inc.; Sofamor-Danek Group, Inc.; Sofamore, S.N.C.; DePuy-Motech, Inc.; Scientific Spinal; Smith & Nephew Richards, Inc.; Synthes (U.S.A.); Synthes, Inc.; Synthes North American, Inc.; Synthes, A.G. Chur; Youngwood Medical Specialities, Inc., f/k/a National Medical Speciality, Inc., f/k/a Stuart Medical Speciality, Inc.; Zimmer, Inc., Defendants.

CIVIL ACTION NO. A96 465 CIV (HRH)
EDPA 97-1488
JURY TRIAL DEMANDED

COMPLAINT
Filed Dec. 2, 1996

* * * General Statement of Facts and Regulatory Background

46. AcroMed designed, manufactured, and then unlawfully promoted, marketed, distributed and sold a variety of pedicle screw fixation devices for surgical implantation into the spine, including the device implanted in Plaintiff's spine.

47. Others, including Ace Medical Company ("Ace"), Advanced Spine Fixation Systems, Inc. ("ASFSI"), Cross Medical Products, Inc. ("Cross"), Danek Medical, Inc. ("Danek"), Sofamor, Sofamor-Danek Group, Inc. ("Sofamor-Danek"), DePuy-Motech, Inc. ("DePuy"), Scientific Spinal, Smith & Nephew Richards, Inc. ("SNR"), Synthes and Zimmer, Inc. ("Zimmer"), designed, manufactured, and then unlawfully promoted, marketed, distributed and sold a variety of pedicle screw fixation devices for surgical implantation into the spine.

48. AcroMed's pedicle screw fixation devices were and are known as the Nested Bone Plate; Cancellous Bone Screw; Variable Screw Placement ("VSP") Spinal Fixation System; Titanium VSP Bone Plates and Bone Screws; and ISOLA System, all of which are medical devices that are regulated by the Food and Drug Administration ("FDA") and governed by the Food, Drug and Cosmetic Act ("FDCA") and the Medical Device Amendments ("MDAs") thereto.

49. Pedicle screw fixation devices were designed and intended to be used in spinal fusion surgery in which surgical techniques are applied to cause two or more vertebrae to fuse together in order to correct various conditions involving spinal instability or deformity. Generally, these devices consist of components such as plates or rods which are attached posteriorly along the vertical axis of the spine with screws inserted into the vertebral pedicles.

50. Pedicle screw fixation devices have been classified by the FDA as Class III devices which "present a potential unreasonable risk of illness or injury" and therefore must receive premarket approval from the FDA before they may be commercially distributed or sold.

51. The FDA may not grant premarket approval for a Class III device unless it determines that there is "reasonable assurance that such device is safe and effective under the conditions of use prescribed recommended or suggested in the proposed labeling thereof."

52. An applicant for premarket approval must furnish the FDA with safety and efficacy data from non-clinical laboratory studies and controlled prospective studies conducted in accordance with protocols approved by the FDA.

53. If a manufacturer wishes to generate the scientific data necessary to obtain premarket approval and thereby market a Class III medical device, it may do so only under the Investigational Device Exemption ("IDE") provisions of the MDAs, which permit experimental devices to be used in humans, without premarket approval, under stringent conditions established and actively supervised by the FDA.

54. When the FDA grants an IDE for a Class III medical device, the device is considered an "investigational device" only. Therefore, under the FDA regulations "the IDE sponsor, the IDE investigator, or any person acting for or on behalf of a sponsor or investigator" may not "promote or test market an investigational device, until after the FDA has approved the device for commercial distribution." Moreover, under the FDA regulations "the IDE sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator" may not "represent that an investigational device is safe or effective for the purposes for which it is being investigated."

55. All devices which were in commerce prior to the effective date of the MDA, May 28, 1976, may remain in commerce without further regulatory action by the FDA.

56. Devices not in commerce prior to May 28, 1976 are presumptively Class III devices and may not be introduced into commerce without premarket approval unless:

(a) the new device is reclassified into Class I or Class II by the FDA in response to a reclassification petition, or

(b) the FDA determines that the device is "substantially equivalent" to a "predicate device," which is a device that was in commerce prior to May 28, 1976 or that was introduced thereafter and was reclassified as a Class I or Class II device.

57. In the event a marketer of a new medical device claims the device is substantially equivalent to a predicate device, it must submit a premarket ("510(k)") notification to the FDA advising the agency of its intent to market the new medical device. In response to such a notification, the FDA will determine whether the device is substantially equivalent to a predicate device. An FDA determination of substantial equivalence is colloquially known as "510(k) clearance."

58. A new device is not "substantially equivalent" to a predicate device unless the device has the same intended use as a predicate device.

59. The FDA defines "intended use" in relation to the labeling of medical devices as:

> [T]he objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

60. Different intended uses for the same physical apparatus give rise to different devices, each of which must receive premarket approval or clearance by the FDA pursuant to a 510(k) notification.

61. Thus, it is unlawful for any person to market, sell, or otherwise introduce into commerce a new Class III medical device for an intended use unless it has received premarket approval or 510(k) clearance for that intended use.

62. Under the FDCA, the "following acts and the causing thereof" are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any...device...that is adulterated or misbranded;

(b) The adulteration or misbranding of any...device...in interstate commerce;

(c) The receipt in interstate commerce of any...device... that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. 21 *U.S.C.* § 331.

63. Violation of these prohibitions is a crime. 21 *U.S.C.* §333.

64. Under the FDCA, "a...device shall be deemed to be adulterated" with respect to an intended use if it is a Class III device which has not received premarket approval or 510(k) clearance with respect to that intended use. *See* 21 *U. S. C.* §351(f).

65. The FDCA expressly provides that "a ...device shall be deemed to be adulterated...if it is a device for which [an investigational device] exemption has been granted...and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by [the FDA]." 21 *U.S.C.* §351(i). This means that a device is adulterated if an IDE sponsor, an IDE investigator, or any person acting for or on behalf of a sponsor or investigator promotes a device for an investigational use or represents that an investigational device is safe or effective for the purposes for which it is being investigated in violation of the FDA's regulations governing IDEs. 21 *C.F.R.* §812.7(a) and (d).

66. The FDCA provides that "a...device shall be deemed to be misbranded" unless its labeling bears "adequate directions" for the intended use of the device including indications, effects, relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purposes for which it is intended. *See* 21 U.S.C. §352(f) and 21 *C.F.R.* §§801.4 and 801.109.

67. Prior to 1984, pedicle screw fixation devices were not available or used in the United States.

68. In 1984, AcroMed filed a 510(k) notification seeking permission from the FDA to market a pedicle screw fixation system. Thereafter, other manufacturers and sellers of pedicle screw fixation devices likewise sought clearance from the FDA to market their devices.

69. These new devices, including AcroMed's devices, were of questionable efficacy in comparison to existing methodologies of treatment and presented the following serious potential risks, among others, not posed by existing spine fusion technology:

(a) The relatively small diameter, together with the unpredictable, highly variable and irregular size, contour and spatial orientation of the pedicles of the spine, and the relatively large outer diameter of the pedicle screws make it extremely difficult for even the most experienced and technically capable surgeon to place the screws entirely within the pedicles without having some portion of the screw breach the external walls of the bone.

(b) Placement of pedicle screws may compress a nerve root, the spinal cord, the sinuvertebral nerves, or the nerves in the sympathetic chain, causing irreversible, permanent nerve and tissue damage. Nerve root irritation resulting from malposed pedicle screws may also produce nerve root irritation which results in ill-defined lower extremity symptoms, including pain, without well-defined neurologic deficit.

(c) Mechanical device failures, caused by repeated application of stress to the metallic elements employed within the internal pedicle screw fixation construct due to motion between the vertebrae sought to be fused can result in stress fractures of the mechanical elements, bending of those elements or loosening and pulling out of the pedicle screws, pseudarthrosis or lack of fusion, and injury to the

spinal cord, cauda equina and nerve roots which lie in close proximity to the device elements.

(d) The presence of the devices may cause diminution in bone density, or osteoporosis, which occurs through the biomechanical process known as "stress shielding." This diminution in bone density, in turn, decreases the "purchase" or holding power of the pedicle screws and/or the bone quality of the fusion mass, producing an increased risk of late screw migration, nerve damage and pseudarthrosis.

(e) Pedicle screws create an increased risk of inflammation and fibrosis due to the presence of a foreign material in the body. In addition, the components of pedicle screw fixation devices abrade against each other, causing metal fretting that often produces significant quantities of corrosion products and a severe inflammatory response.

(f) Insertion of pedicle screws and attachment of plates or rods may cause pedicular fracture or pedicular microfracture which is difficult to diagnose post-surgically. The bleeding associated with such fractures adds to scarring and pedicular bulk.

(g) The shape, location, contour and bulk of pedicular hardware causes chronic irritation to the overlying paraspinal muscles producing chronic pain.

(h) The placement of pedicular fixation hardware may destabilize the spine and interfere with the fusion process.

(i) Positioning of the screw in the pedicle may block normal venous channels within the bone leading to increased venous pressure with possible concomitant engorgement or alteration in blood flow, necrosis and injury to surrounding tissues.

(j) Pedicle screw devices create an increased risk of infection. Spinal infections are associated with increased rates of epidural scarring which, in turn, results in the tethering and

compression of nerves and nerve roots which causes disabling pain and dysfunction.

70. Because pedicle screw fixation systems represented a new post-amendment technology which presented health risks not engendered by other spinal fixation systems, the FDA consistently refused to clear any of these devices for market under the 510(k) substantial equivalency process.

71. Beginning in 1984 and continuing through January of 1995, the FDA determined that all spinal fixation systems incorporating pedicle screws were not substantially equivalent to any legally marketed predicate device and were new Class III devices which required premarket approval from the FDA before they could be introduced or delivered for introduction into interstate commerce.

72. In order to permit AcroMed and other manufacturers of such devices to generate scientific evidence necessary to obtain premarket approval, the FDA granted approval to conduct fourteen separate IDE clinical trials for various pedicle screw fixation devices during the period from 1986 through 1993. Each of the pedicle screw fixation devices manufactured by AcroMed was the subject of an IDE.

73. None of these IDEs generated sufficient evidence of safety and efficacy of pedicle screw fixation devices to support a successful application for premarket approval.

74. Accordingly, at all times material to this Complaint it was illegal to sell any device intended as a pedicle screw fixation system or to market or promote any medical device for use with screws inserted posteriorly into the spinal pedicles (apart from devices used in the FDA-approved IDE trials).

75. Notwithstanding this legal prohibition, AcroMed promoted, marketed, distributed, and sold devices which were intended for use as pedicle screw fixation devices on a massive scale outside of any approved IDE in violation of the prohibitions of federal law against adulteration and misbranding.

76. In addition, the remaining Defendants also participated in the promotion, marketing, distribution and sale of devices which were intended for use as pedicle screw fixation devices on a massive scale outside of any approved IDE in violation of the prohibitions of federal law against adulteration and misbranding.

77. As a result, hundreds of thousands of patients, including Plaintiff, were surgically implanted with spinal fixation devices within the pedicles of their spine even though there was inadequate evidence to provide a reasonable assurance that such devices were safe and effective when used in that. manner.

Count 1: Fraud (on the FDA)

78. Plaintiff realleges each and every allegation set forth in the Paragraphs above and farther alleges as follows:

79. The claims made in this Count of the Complaint are brought by Plaintiff against AcroMed, Steffee, and Buckman.

80. Arthur D. Steffee ('Steffee") formed AcroMed in 1983 in order to manufacture and sell orthopedic devices and specifically pedicle screw implants and instrumentation.

81. Steffee has remained the controlling shareholder in AcroMed and a member of its Board of Directors from the inception of the company through the present.

82. In 1983, Steffee developed the VSP spinal plate fixation system for use solely in spinal fusion surgery and not for repairing fractures in bones outside of the spine. The device consisted of slotted plates which were intended to be attached along the vertical access of the spine with screws inserted posteriorly into the spinal pedicles.

83. AcroMed began selling the VSP device in interstate commerce in early 1984 without filing a Section 510(k) premarket notification as required by federal law.

84. On September 4, 1984, AcroMed sought to cure this violation by filing a 510(k) premarket notification for the VSP device. This notification represented accurately that the device was intended for use in spinal surgery.

85. On December 19, 1984, the FDA determined that the VSP device was a Class III device which was not substantially equivalent to any device marketed in interstate commerce prior to May 28, 1976 and therefore could not be commercially distributed without premarket approval.

86. Thereafter, AcroMed continued to commercially distribute its VSP system without applying for or obtaining premarket approval.

87. In March of 1985, AcroMed met with Carl Larson at the FDA and was told that the clinical data which AcroMed had submitted in its premarket notification were suspect and insufficient in that they came only from Steffee who had a financial interest in the commercial exploitation of the device and they revealed a twenty percent (20%) device failure rate, and, therefore, the FDA could not make a determination concerning the device's safety and effectiveness.

88. Thereafter, AcroMed filed another 510(k) premarket notification on September 20, 1985, supplying the FDA with additional data. This notification again accurately stated that the device was intended for us in spinal fixation surgery.

89. In response to this 510(k) notification the FDA again determined that the device was not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 and posed potential risks not exhibited by other spinal fixation systems, and, therefore, the VSP device was a Class III device which could not be legally marketed without premarket approval.

90. Determined to "immediately sell the VSP system for spinal fixation," AcroMed hired Buckman Company, Inc. ("Buckman"), and together with Steffee, they concocted and agreed to an unlawful and deceptive scheme in the fall of 1985 to bring the VSP spine plate fixation device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

91. The unlawful plan contemplated that:

(a) AcroMed would fraudulently seek 510(k) clearance of the components of the VSP system as bone plates and bone screws to be used in repairing fractures of the long bones, even though the sole intended use of these components was as an assembled spine plate/pedicle screw fixation system;

(b) Once clearance from the FDA had been obtained, AcroMed would contend that "FDA's determination of substantial equivalence constitutes official notification from the FDA that the devices are safe and effective and that such devices may be introduced commercially for medical use";

(c) Consistent with AcroMed's goal to sell the VSP device in interstate commerce, AcroMed would promote the cleared device components for use solely in spinal applications by using physicians such as Steffee to train other physicians in spinal applications of the device components as a spine plate/pedicle screw fixation system.

92. In accordance with this plan to deceive the FDA and ultimately the public in order to obtain 510(k) clearance for the VSP device, AcroMed changed the name of the VSP device from a "spinal plate fixation system" to "nested bone plates" and "cancellous bone screws."

93. On December 20 and December 30, 1985, respectively, AcroMed submitted two separate 510(k) premarket notifications to the FDA for the plate and screw components of the VSP system, omitting all references to the use of the device in the spine and falsely representing to the FDA that the device components were substantially equivalent to pre-amendment Class II devices used in the repair of fractures of the long bones of the arms and legs.

94. In response to the FDA's inquiry concerning the intended use of the bone plates and bone screws, on January 10, 1986, Buckman, acting as a representative for AcroMed and with AcroMed's knowledge, intentionally and falsely represented to the FDA

that "[t]he proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates...[and] are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)."

95. AcroMed, Buckman and Steffee intended for the FDA to clear the VSP device components based upon this misrepresentation.

96. In reliance on this express misrepresentation, the FDA determined in January, 1986 that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 for the intended use represented by AcroMed.

97. AcroMed's president, Ed Wagner, admitted in a letter which he wrote on January 16, 1986 that this representation to the FDA was false — that AcroMed sought approval of its VSP plates and screws for use in the long bones simply as a pretext in order to market the device for its true intended use in the spine.

98. In addition, AcroMed's Vice President and Chief Counsel, Geoffrey Porter, admitted under oath that the **only purpose** for which AcroMed's plates and screws were sold was for use in the spine.

99. Steffee also has admitted that the VSP device was intended exclusively for use in the spine and not as a general orthopedic implant.

100. In January of 1986, AcroMed applied for an IDE to conduct clinical trials of the VSP device in the human spine. In its IDE application, AcroMed acknowledged to the FDA that spinal application of the VSP device was "experimental" and affirmatively represented that the device would not be employed in spinal procedures on any patients other than the 250 patients participating in the IDE study.

101. Nevertheless, AcroMed marketed and promoted the VSP device on a massive basis outside of its IDE trial solely for that prohibited use.

102. Due to serious problems with the VSP IDE trials, the FDA, in April of 1990, withdrew approval of AcroMed's IDE because according to the FDA "continuing of testing under the exemption [would] result in an unreasonable risk to the public health," and "the rights, safety and welfare of the patients in this investigation [were] not being protected and there [was] reason to believe that the scientific soundness of this investigation [had] been compromised."

103. On November 30, 1987, AcroMed submitted a 510(k) notification to the FDA with respect to an "integral nut" screw which was a revised version of the cancellous bone screw for which AcroMed had received 510(k) clearance in January, 1986.

104. In the 510(k) notification which AcroMed submitted for the integral nut screw, AcroMed knowingly and falsely represented to the FDA that the screw was intended for general orthopedic applications and not intended for use in the pedicles of the spine.

105. This representation was false.

106. Indeed, at the time AcroMed made this representation, AcroMed intended that the integral nut screw be used in the pedicles of the spine as a point of attachment for both AcroMed's VSP bone plates and the rods of the ISOLA spine fixation system which it had been developing.

107. AcroMed intended that the FDA clear this screw for marketing based on AcroMed's 510(k) submission.

108. As a result of and in reliance on these misrepresentations to the FDA concerning the intended use of AcroMed's integral nut screw, the FDA issued a 510(k) clearance for non-pedicle uses of the bone screw on January 20, 1988.

109. Beginning in 1985 and continuing through 1990, Marc Asher ("Asher"), together with William C. Carson ("Carson") and Charles Heinig ("Heinig"), shareholders in ISOLA Implants, Inc., developed the ISOLA Spine Fixation System, to serve as a spinal

fixation device using rods and VSP pedicle screws generally as well as hooks for certain limited indications.

110. AcroMed employed Buckman to assist it in successfully bringing ISOLA to market, using the same fraudulent scheme they had used with the VSP device.

111. Specifically, on June 27, 1988, Buckman, on behalf of AcroMed, submitted an IDE application for ISOLA to the FDA which admitted that the "ISOLA Spine System uses pedicle screws as the point of fixation."

112. Shortly thereafter, on September 29, 1988, Buckman submitted three separate 510(k) premarket notifications for components of the ISOLA system: the "iliac screw, the Eye Rod, and spinal rod and hooks."

113. None of these premarket notifications admitted that the device components were to be used in connection with pedicular fixation, but instead falsely claimed substantial equivalence to fixation devices used for attachment to the spine with hooks or with screws inserted in locations other than the pedicles of the spine.

114. In response to the FDA's expressed desire to combine the three 510(k)s so it could ask questions about the components as an entire system, Buckman advised AcroMed that "it is to Acro-Med's advantage to get each component approved separately. By maintaining the individual 510(k)'s, we can assert that any system questions are not relevant...," and "the trick will be in convincing the FDA that the components are not a system and therefore should be evaluated individually."

115. In accordance with AcroMed's plan to deceive the FDA and ultimately the public, AcroMed and Buckman submitted three separate false and/or deceptive responses to the FDA, each answering those questions that applied to the related device component submissions.

116. For example, Buckman claimed falsely that since the iliac screw was to be marketed separately, "[i]ts substantial

equivalence should be determined as an individual device not as a component part...."

117. AcroMed and Buckman intended that the FDA clear the components of the ISOLA system based on the 510(k) submissions.

118. In reliance on AcroMed and Buckman's express misrepresentations, on April 26, 1989, the FDA granted 510(k) marketing clearance for the ISOLA spinal rods and hooks, and on May 3, 1989, the FDA granted 510(k) clearance for the iliac screw.

119. The FDA informed AcroMed that the iliac screw "may not be labeled or promoted for pedicular attachment to, or fixation of, the spine," and "all labeling for this device, including package label and labeling included within the package, must prominently state that the screws of this device are intended for sacral/iliac attachment only" and labeling must include the statement: "WARNING - THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION."

120. In furtherance of their unlawful plan to market pedicle screw fixation devices, in the early part of 1990, AcroMed, ISOLA Implants, Inc. and Asher made certain changes to the components of the ISOLA system creating slotted connectors for the specific purpose of permitting a surgeon to connect ISOLA rods to VSP screws inserted in the spinal pedicles.

121. On January 27 and December 28, 1990, AcroMed submitted 510(k) notifications for the ISOLA slotted connectors, in which it knowingly made a false representation that "the connectors are for use when the stabilization of the spine requires anchoring through the ilium/sacrum," and in which it falsely disclaimed any intended use in connection with pedicle screws.

122. On March 14, 1991, AcroMed knowingly made a false representation to the FDA that the slotted connectors were intended to be used only with the components of the ISOLA system, and not with any other system including the bone screws developed for pedicular attachment to the VSP system.

123. AcroMed intended that the FDA clear these slotted connectors for marketing based upon these 510(k) submissions and AcroMed's misrepresentations concerning the intended use of the slotted connectors.

124. In reliance on AcroMed's misrepresentations, the FDA issued a 510(k) clearance for the ISOLA slotted connectors on March 21, 1991, which expressly stated that if AcroMed labeled or promoted the devices for pedicle screw fixation, the devices would be adulterated in violation of federal law.

125. AcroMed's and Buckman's representations to the FDA with regard to the intended use of the ISOLA system and its components were plainly false and misleading.

126. Asher conceded that the ISOLA system was a pedicle screw system designed and developed for use with AcroMed's VSP pedicle screws.

127. Indeed, Asher developed a technique manual, a videotape, and a distributor notebook, all of which demonstrated pedicle screw fixation with the ISOLA device and each of which was customarily provided to surgeons and/or distributors in the United States.

128. In addition, AcroMed and Isola Implants, Inc. entered into a royalty arrangement expressly contemplating payment of a royalty on "sales of AcroMed integral nut pedicle screws" for use with the ISOLA system both within the limited ISOLA IDE and for "commercial sales" outside of the ISOLA IDE.

129. Consistent with the intention that the ISOLA system be used for pedicular attachment to the spine with VSP screws, AcroMed actively marketed, promoted, distributed, and sold the device for that purpose on a massive basis outside of the ISOLA IDE.

130. The misrepresentations by AcroMed, Steffee, and Buckman as described in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the VSP and ISOLA devices and device components

in order to provide a pretext to claim that the devices could be lawfully introduced in interstate commerce.

131. The FDA was ignorant of the fact that these devices and device components were intended by AcroMed to be used as pedicle screw fixation devices.

132. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for AcroMed's pedicle screw fixation devices for any purpose, the devices would not have been introduced into interstate commerce, and Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff's spine.

133. The FDA, Plaintiff and Plaintiff's implanting physician relied upon these Defendants to make truthful statements to the FDA in their 510(k) notifications regarding the intended use of the device at issue so that Plaintiff would not be implanted with a defective medical device that was never proven to be safe and effective for the use for which it was intended, i.e. pedicle screw fixation.

134. As a direct and proximate result of the wrongful conduct alleged in Count I of this Complaint, Plaintiff has suffered, and will continue to suffer, severe physical harm, including injury to Plaintiff's spine, spinal nerves, spinal nerve roots, and surrounding nerves, tissues, cells, and vascular structures. As a result, Plaintiff has in the past and will in the future sustain and suffer a loss of earnings, an impairment in earning capacity, severe physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitative expenses, and other forms of injury, loss and damage.

* * * *

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

AcroMed's Motion for Summary Judgment or Partial Summary Judgment on the Grounds of Preemption or Deference to Agency Expertise

Filed April 17, 1995

[Text of Motion omitted]

Affidavit of William Christianson

[Text of affidavit and Exhibits 1-19 omitted]

Exhibit 20 to Affidavit of William Christianson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD

May 3, 1989

Joyce L. Bromm, R.N., J.D.
Buckman Company, Inc.
Representing AcroMed Corporation
921 Calle Verde
Martinez, California 94553

Re: K884161
AcroMed Iliac Screw
Regulatory Class: II
Dated: February 1, 1989
Received: February 2, 1989

Dear Ms. Bromm:

We have received your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on posterior spinal fixation/stabilization devices being equivalent only to similar devices labeled and intended to be fixed to the spine by laminar hooks and sacral/iliac attachment. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for pedicular attachment to, or fixation of, the spine.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the screws of this device are intended for sacral/iliac attachment only and include the statement: "WARNING – THIS DEVICE HAS NOT BEEN APPROVED FOR PEDICULAR APPLICATION."

3. Any pedicular fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for pedicular attachment/fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

You may market your device under the above limitations as a class II device. If you market this device with any claims or indications

other than as a posterior laminar hook attachment system, the device would be considered class III and as such it would be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, REgulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

/s/
Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Reply Memorandum To Motion By United States
Of America On Behalf Of The Food And Drug
Administration For Protective Order

Filed August 10, 1995

[Text of Reply Memorandum omitted]

EXHIBIT A
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

[Caption omitted]

NOTICE OF DEPOSITIONS

PLEASE TAKE NOTICE that plaintiffs in the above-entitled action will take the depositions, upon oral examination, of the following persons on the dates, at the times and in the places listed. The depositions are being taken pursuant to Paragraph 2 of Pretrial Order No. 51. At each deposition, each witness shall be required to produce those documents listed in Schedule "A" to this Notice. The depositions shall take place before a Notary Public and shall be stenographically transcribed and may also be recorded by videotape

Name of Deponent	Date and Time of Deposition	Place of Deposition
David A. Murray	* * *	
Paula Wilkerson	* * *	
Bernard F. Morrey	* * *	

Michael D. Mayor ***
Daniel R. Benson ***
Thomas Whitecloud ***
Mark Melkerson ***
William J. Kane ***
Nirmal Mishra ***
Curtis Dickman ***
Martin Yahiro ***
Alvin Crawford ***
Hansen Yuan ***
Steven Mardjerko ***
Thomas Zdeblick ***
Leela Rangaswany ***
Steven Garfin ***
Claudia Thomas Cartie ***
Seth Greenwald ***
Edward N. Hanley ***
Christine Incorvaia ***
Philip Molgren ***

By: _____
Arnold Levin
Liaison Counsel
PLAINTIFFS' LEGAL COMMITTEE

SCHEDULE "A"

I. DEFINITIONS

As used herein, the following terms have the following meanings:

1. The term "document is used in its broadest possible sense to refer to any document or other tangible matter or thing which may be properly subject to a request under the Freedom of Information Act and your implementing regulations.

2. The term "Cohort Study" refers to the historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar and Sacral Spine Fusions, the results of which were reported to the Orthopedic and Rehabilitation Devices Advisory Committee Panel meeting on July 22, 1994 and in the October, 1994 supplement to *Spine* magazine.

3. The term "relevant premarket notifications" refers to all premarket notifications submitted under Section 510k of the Food, Drug and Cosmetic Act at any time from January 1, 1993 through the present in which the intended use of the device was posterior attachment to the spine by means of screws inserted through the spinal pedicles.

II. DOCUMENTS REQUESTED

1. All documents reflecting, relating or referring directly or indirectly, to the Cohort Study.

2. All documents reflecting, relating or referring to each and every event involved in planning for the Cohort Study, including any plans or protocols which were abandoned or not otherwise carried out.

3. All documents reflecting, relating or referring to the implementation of any plans for the Cohort Study including transactions undertaken and ultimately not included within the study.

4. All documents reflecting, relating or referring to any results of the Cohort Study including, without limitation, results which were not reported as part of the study.

5. All documents reflecting, relating or referring to any communications among any persons including physicians, organizations of physicians, manufacturers, organizations of manufacturers, the Food and Drug Administration, the National Institute of Health, and any other person, entity or organization with regard to the Cohort Study.

6. All documents reflecting, relating, or referring, directly or indirectly, to the payment of money or any item of value to or for the benefit of any person in connection with the Cohort Study.

7. All documents reflecting, relating or referring, directly or indirectly, to clinical data solicited in connection with the Cohort Study.

8. All documents reflecting, relating or referring, directly or indirectly, to the analysis, review, audit, retention and/or destruction of any clinical data solicited or received in connection with the Cohort Study.

9. All documents reflecting, relating or referring to the identity of each and every person who was involved in any aspect of the Cohort Study.

10. All documents reflecting, relating or referring to any audit procedure which was proposed or implemented in connection with the Cohort Study.

11. All documents reflecting, relating or referring to any analysis, summary or meta-analysis of literature with regard to the subject of pedicle screw fixation which was used or proposed to be used in connection with the Cohort Study including analyses used for purposes of selecting study "controls," and meta-analyses and summaries presented or proposed to be presented to the July 22, 1994 Advisory Panel meeting.

12. All documents reflecting, relating or referring to the identity of each physician who submitted data in connection with the Cohort Study.

13. All documents reflecting, relating or referring to any transaction in which any FDA employee or consultant and/or physician and/or entity who supplied data in connection with the Cohort Study received or had a relative or entity with which he was affiliated receive money, securities, items of value or the promise of money, securities or other items of value, contingent or otherwise, from any member of the Spinal Implant Manufacturers Group.

14. All documents reflecting, relating or referring, directly or indirectly, to directions, instructions, protocols, procedures, or the like in connection with the Cohort Study.

15. All data derived from the Cohort Study in the form of computer tapes, disks, diskettes, hard drive, or other electronic storage media together with such documents as are necessary for the complete understanding of the manner in which such data have been stored and may be effectively retrieved.

16. All documents reflecting, relating or referring to each and every "control" used in connection with the Cohort Study.

17. All documents reflecting, relating or referring to the payment of money, the conveyance of anything of value or the promise of such payment or conveyance, contingent or otherwise, by any person to or for the benefit of any FDA consultant or any employee of the FDA in connection with the Cohort Study.

18. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant, on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Scoliosis Research Society and/or the American Association of Orthopedic Surgeons, on the other ha[n]d, with respect to the subject of the pedicle screw fixation and/or the regulation thereof.

19. Each of the relevant premarket notifications.

20. All documents reflecting, relating or referring to the FDA's consideration of each of the relevant premarket notifications.

21. All documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon.

22. All documents reflecting, relating or referring to each "predicate device" for which substantial equivalence was claimed in each of the relevant premarket notifications.

23. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sc[olio]sis Research Society and/or the

American Association of Orthopedic Surgeons, on the other hand, with respect to each of the relevant premarket notifications.

24. All documents reflecting, relating or referring to the payment of money or the conveyance of any thing of value to or for the benefit of any FDA employee or consultant in connection with any of the relevant premarket notifications and any agency action thereon.

25. All documents which reflect any agency action on each of the relevant premarket notifications.

26. All documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications including any agency determination to "clear" a device for use in the human pedicles.

27. All calendars, log books, telephone logs, or other documents reflecting the daily activities and conduct of each deponent to whom this Notice of Deposition and the Subpoena Duces Tecum is addressed during the period from January 1, 1993 through the present.

28. All documents reflecting any FDA analysis of data with respect to spinal fixation devices which was generated pursuant to Investigational Device Exemptions granted to Acromed, Inc., Buckman & Company, Sofamor, S.N.C., Stuart, Smith & Nephew Richards, Inc., Zimmer, Advanced Spine Fixation System, Inc., and/or Cross Medical Products.

[Exhibits B and C omitted]

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

DECLARATION OF KATHLEEN L. WALKER

Pursuant to the provisions of 28 U.S.C. § 1746, I, Kathleen L. Walker, declare as follows:

1. I have been employed by the Food and Drug Administration ("FDA") since August 1983. I started with FDA as a nurse consultant in the Office of Device Evaluation ("ODE"), Center for Devices and Radiological Health ("CDRH"). I currently hold the position of Committee Management Officer in the Office of Management Services ("OMS"), CDRH. My responsibilities in this position are to provide administrative and program support to ODE in connection with the Medical Devices Advisory Committee, to prepare requests for personnel actions for Special Government Employees ("SGEs") in order to staff the committee, and to review the financial interests of SGEs to determine if there is a conflict of interest relating to a particular matter to be reviewed for a meeting or a special assignment.

2. FDA, which is a division of the Department of Health and Human Services, is responsible for ensuring the following: that foods are safe, wholesome, and sanitary; that human and veterinary drugs, biological products, and medical devices are safe and effective; that cosmetics are safe; and that electronic products that emit radiation are safe. Further, FDA is responsible for ensuring that regulated products are honestly and accurately represented to the consuming public and to health professionals.

3. CDRH is responsible for protecting the public health by helping to ensure that medical devices are safe and effective and that radiation exposure from electronic products is kept to a minimum. CDRH evaluates new medical devices for safety and effectiveness, and classifies new devices according to a regulatory scheme established under the Food, Drug, and Cosmetic Act ("the Act"). CDRH works with other divisions of FDA to initiate enforcement actions against products and manufacturers which are not in compliance with the Act.

4. ODE is principally responsible for evaluating the safety and effectiveness of medical devices before they are cleared for clinical research and marketing.

5. As a scientific regulatory agency, FDA and, in particular, CDRH, requires access to highly qualified expert advisors who can provide scientific and technical advice. Thus, FDA and CDRH use advisory committees (or advisory panels) to supplement the Agency's internal expertise and help the Agency staff stay current with "state-of-the-art" technology.

6. One such advisory committee is the Medical Device Advisory Committee, which is comprised of sixteen advisory panels (such as the Orthopedic and Rehabilitation Panel) . The panels review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation. Each panel, according to its specialty area, performs the following tasks: to advise the Commissioner of FDA regarding recommended classification or reclassification of these devices into one of three regulatory categories; to advise on any possible risks to health associated with the use of devices; to advise on formulation of product development protocols; to review premarket approval applications for medical devices; to review FDA guidelines and guidance documents; to recommend exemption of certain devices from the application of portions of the Act; to advise on the necessity to ban a device; and to respond to requests for the FDA to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. Each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of FDA on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

7. FDA's advisory committee members are appointed as SGES. An SGE is anyone who is retained, designated, appointed, or employed to perform temporary duties whether on a full-time or intermittent basis with or without compensation, for a period not to

exceed 130 days during any period of 365 consecutive days. This includes panel members, consultants, and experts.

8. All SGEs (who may serve as voting panel members, consultants, or experts to advisory committees) receive compensation for each day worked, including travel and per diem, unless such compensation and reimbursement is waived.

9. Finding qualified experts to continually staff the 148 member roster of the Medical Devices Advisory Committee is a difficult and time-consuming process. Relatively few individuals in this country possess the requisite background to serve on advisory panels, and can offer the kind of expertise which is needed to make the sophisticated judgments involved in medical device evaluation and classification. Moreover, many qualified experts choose not to participate on panels because the financial compensation is minimal and the inconveniences (time and travel) for participating on panels are often great.

10. Because advisory committees play such an important role in new product evaluation and classification, and because there is a limited pool of qualified experts who are able to serve on these panels, CDRH is very concerned about the implications of having panel members provide testimony in private litigation to which the federal government is not a party.

11. FDA and CDRH have several significant grounds for opposing the depositions of panel members. First, advisory panel members are provided access to confidential commercial information which relates to the products under evaluation and which the agency has a duty to protect. Second, CDRH is troubled by the prospect that qualified experts will simply choose not to serve on panels if they know that, as result of their service on the panels, they may be compelled to provide testimony in litigation to which they are not a party; indeed, in the past several panel members have expressed such concerns. This is especially true in cases such as this where all of the subpoenaed panel members are surgeons or professors who have extremely demanding schedules. Finally, many of the records

concerning the findings and recommendations of the panel are publicly available and, to the extent that they are publicly releasable, would be available to the litigants pursuant to a proper request.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 9th day of August, 1995.

/s/
KATHLEEN L. WALKER
Committee Management Officer
Office of Management Services
Center for Devices and Radiological Health
Food and Drug Administration

[Exhibits E and F omitted]

EXHIBIT G
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

DECLARATION OF LEELA RANGASWAMY, M.D.

Pursuant to the provisions of 28 U.S.C. § 1746, I, Leela Rangaswamy, declare as follows:

1. I am currently employed as an Orthopedic Surgeon at the Harvard Community Health Plan, in Boston, Massachusetts, and as a Staff Attending Orthopedic Surgeon at the Children's Hospital in Boston, Massachusetts. I serve as the Deputy Editor for the Journal of Bone and Joint Surgery. I am also a board examiner for the American Board of Orthopedic Surgery.

2. I received medical degrees from the Madras Medical College, Madras, India, and from the University of Delhi, Delhi,

India. I am licensed to practice medicine in New York, Delaware, and Massachusetts. I am board certified in orthopedic surgery.

3. I began a term as a Special Government Employee ("SGE") for the United States Food and Drug Administration ("FDA") on June 26, 1994. My term will end on August 31, 1998.

4. As an SGE, I am asked by FDA to perform temporary duties on an intermittent basis. I receive compensation for each day worked, including travel and per diem, unless such compensation and reimbursement is waived.

5. My employment as an SGE has been limited to serving as a panel member on the Orthopedic and Rehabilitation Devices Panel Meeting of July 21 and 22, 1994. This panel reviewed and evaluated data on the safety and effectiveness of marketed and investigational medical devices and made recommendations for their regulation.

6. I offered my services to act as an SGE because I believe that FDA advisory panels serve the public health through the review and evaluation of new medical devices. When I applied for the position, I did not anticipate that I would be required to provide deposition testimony in a private lawsuit regarding my work as a panel member.

7. My duties as a surgeon at two medical institutions and as an editor of a major medical journal demand a great deal of time and commitment. Although I believe that the work performed by the FDA advisory panels is a much needed public service, I would be hesitant to serve on future advisory panels if I knew that, as a consequence of such participation, I would be required to devote additional time providing testimony in private lawsuits.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5th day of August, 1995.

/s/
Leela Rangaswamy, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Transcript of Hearing Before Hon. Louis C. Bechtle, S.J.
August 17, 1995

* * * [154] * * *

THE COURT: The plaintiffs aren't worried. What they do, they do. What they presumably have to do in keeping with, I think, their reputation, they have had that many years, they may do the right thing. This may be of help, maybe not. It seems to me that a limited deposition — I say limited, possibly no more than a day, depending on what the answers are, it could be very short depending on the answers, it could be lengthy depending on the answers.

It seems to me that you have persons here who are, if you will, entangled with others. There is sufficient showing in the Court's view to have these depositions go forward.

Now, I worry a little bit, I wouldn't

[155] allow them to produce their patient calendars, because identification of patients is irrelevant. That thing would be obviously protected against the extent they need their own calendars, where they were, what they did, how they finished, and that would seem to be pertinent.

I don't see how that is difficult. Persons in high position have to understand occasionally within limits they will have to be, to some extent, inconvenienced.

Now, if doctors have a surgical schedule on a certain day or have to meet with the FDA, there's no question that those dates should be considered when arriving at these depositions.

I just don't think these persons are entitled to have — I have some doubt if there is a status of clothed agencies whose depositions are disfavored. I don't think these persons are in that status.

I think I tried to explain the reason why they are entitled to be deposed courteously, but I think firmly, fairly and fully in keeping with what has been requested here. * * *

[156] * * *

THE COURT: I don't think we, you and I, disagree from late '93 up to late '94 as kind of an industry, professional and government agency kind of affiliation that brought about a recommendation that this device be placed in a more favorable category from the vantage point of marketing.

Now, included in that affiliation were a number of persons. It hasn't been proven, but there is a sufficient showing here that substantial things of value passed to them or to the parties or persons that they worked for or their superiors of value from the industry.

[157] Now, without more, it seems to me, that just casts a shadow on the impartiality of their votes and their consultation on July 22 of 1994. Maybe there's nothing to it. I think the pointing of the questions the way they were suggested on these topics that have been mentioned, I think will bring it out promptly and presumably, if Dr. X or Y, including this five, this is my file in the Cohort, this is my file under oath, what I know, my viewpoint, I'm an advocate of this. I don't care about bias as it relates to the downgrading of the device from the vantage point of the professional standing of the individual. If a doctor has a belief in these devices, believes they should be downgraded, I don't have a problem with that. We have the suggestion, some persons close to it in higher position not on this list, were making decisions and at the same time receiving some benefit or some value or some advantage from those that will profit from this marketing. That, in my view, is sufficient need to allow the interest in protecting government's employees from testifying being relaxed to the extent that the plaintiffs seek to relax it, excluding inquiry concerning FDA acquired knowledge, FDA deliberations which the

[158] statute requires. * * * *

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Plaintiffs' Substituted Brief in Opposition
to AcroMed's Motion for Summary Judgment
or Partial Summary Judgment on the Grounds of
Preemption or Deference to Agency Expertise

Filed October 13, 1995

[Text of Brief omitted]

EXHIBIT 1
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA
NEW ORLEANS

DOROTHY MARIE REEVES	:CIVIL ACTION :91-4689 "H"
VERSUS	:
ACROMED CORPORATION, ET AL.	:New Orleans, :Louisiana :Tuesday, August 30, 1993 :8:30 a.m.

Volume I of III

TRIAL BY JURY

BEFORE THE HONORABLE ADRIAN G. DUPLANTIER,
UNITED STATES DISTRICT JUDGE, presiding

* * *

[68] GEOFFREY J. PORTER, PLAINTIFF'S WITNESS,

SWORN CROSS-EXAMINATION * * *

Q. What is your position with AcroMed Corporation?
A. I'm vice-president and general counsel.
Q. You are also a stockholder in AcroMed Corporation, sir?
A. Yes, sir.
Q. Now, sir, what is AcroMed Corporation? What do you all do?
A. Manufacture and sell orthopaedic devices, specifically spinal implaints and instrumentation. * * *
[92] Q. Well, let me first ask you, sir, who is Mr. David Schlerf?
A. He works for the Buckman Company.
Q. Who is the Buckman Company?
A. The Buckman Company was the consultant of AcroMed at that time for FDA matters. * * *

[Testimony of Norman Welford]
[126] Q. Now, when did you first see this letter of January 10th, 1986?
A. Is that the letter from Schlerf?
Q. Yes, sir.
A. I have looked at the 510k which had been sent to me by Mr. Tschirn, and I noticed that this did not have many of the documents which one normally gets into a 510k when one is at FDA. One has the application from the manufacturer, and then one has comments and a sign-off sheet as it were with, maybe a few notes on it. So, I saw that there is a company in Washington which supplies copies under the Freedom of Information Act of 510k's. If they have them in stock, as it were, then you can get this very quickly. I called them and ordered this, actually, at the end of July, and they sent it down to me, and in that I found there was more information than I had previously from Mr. Tschirn.

[127] And in that were the notes of the reviewer who said "yes, this is the same thing as the VSP spinal plate." What I needed to clear up was what they intend to use this for.

So, in the normal course of events, what one does is, one just calls the company and says – in this case, the Buckman Company who was representing Acromed – and said to them "look, what is the intended use for this plate? I need a statement."

Q. So, why is it important for that reviewer to say "what is the intended use"?

A. Well, because as this had been declared what FDA calls NSE, or not substantially equivalent when it came in as the VSP spinal plate, then if this new application was for the same intended use as the previous one, it also would have been not substantially equivalent.

Q. So, if they stated that the 510k application with regard to December 20th and December 30th, 1985, was for spinal usage, then, in your opinion, would that have been approved or not?

A. In my opinion, it certainly would not have been approved.

Q. Just as the others had not been approved, is that correct?

A. Yes, correct.

Q. But, when, in response to that question about "what is

[128] the indications for use," when they say that the usage was specifically for arm or leg fractures or pelvis fractures, is that a different use than for the spine?

A. Exactly. It is a different use, and marketing permission is only for that use.

Q. So, does that appear when you have a product that is clearly for spinal application, yet Acromed tells the FDA that in their 510k application it is for long bone use, is that deceptive, in your opinion?

A. It would be deceptive if they did not intend to sell that just for long bone use.

Q. And if, in truth and in fact, they clearly intended to sell it, promote it, market it, distribute it for spinal implant, then, in your

opinion, would it be deceptive to tell the FDA that the indications of use are for fractured long bones?

A. If they did not truly intend those indications, of course it would be deceptive. * * *

[204] * * * EDWARD WAGNER, PLAINTIFF'S WITNESS, SWORN DIRECT EXAMINATION

Q. Mr. Wagner, were you ever employed by AcroMed Corporation, the defendants in this case?

A. Yes, I was.

Q. And what was your position with AcroMed Corporation, Sir?

A. President.

Q. And for how long were you president of AcroMed Corporation?

A. From 1983 until 1990. * * *

[206] * * * Q. Okay. Is it true, sir, that AcroMed Corporation was

[207] selling and/or distributing the VSP Spine Plate Fixation System before they even applied for 510K approval?

A. Yes. * * *

Q. I think you told us that as time went on, into the end of 1984 and the beginning of '85, you began selling to more and more doctors and hospitals, is that correct?

A. That's correct. * * *

[212] * * * Q. Now, is it true, sir, that the VSP Spine Plate Fixation System was for application to the spine, this system I'm holding in front of me was for application to the spine?

[213] A. That was its principal purpose. * * *

[229] * * * Q. Was this product marketed for spinal use?

A. Yes.

Q. Did Dr. Steffee make a video tape showing how it is used in the spine?

A. Yes, he did. * * *

[230] * * * Q. Did you know that he obtained a patent for this product for spine application?

A. Yes, yes.
Q. So, isn't the truth, sir, that this is a spine device, and indications for use are not for long bone, but, rather, for the spine? Isn't that the truth?
A. Principally, yes, yes. * * * *

[Testimony of Arthur D. Steffee]
[237] Q. Now, you applied for a patent for the VSP Spine Plate Fixation System, did you not, sir?
A. Through AcroMed, yes, sir. * * *
Q. And is there anything in that patent application that
[238] deals with this product, the VSP Spine Plate Fixation System being applied to an arm or a leg?
A. No, sir.
Q. The patent application is strictly with regard to a spine apparatus, is that correct?
A. That's correct.
Q. Which is what it is entitled on the first page, is that correct?
A. That's right.
Q. And, of course, as you go through the whole patent application, you describe the whole method of applying this to the spine, is that right, sir?
A. That's correct.
Q. Because that's what this product is, isn't it? It's a spine device?
A. It can be used for other reasons, but it is primarily for —
Q. That's not my question.
A. For the spine, yes.
Q. This product was patented by you as a spinal device, wasn't it?
* * *
[245] Q. You are familiar with the fact that in response to both of those applications in '84 and in '85, September of '85, the FDA clearly wrote and stated "Do not commercially distribute or market the product," aren't you?

A. That's what the document says.
Q. Yet, AcroMed continued to distribute and market the product, didn't they?
A. Yes, they did. * * * *

EXHIBIT 2

UNITED STATES PATENT
Steffee
Patent Number: 4,611,581
Date of Patent: Sep. 16, 1986

APPARATUS FOR STRAIGHTENING SPINAL COLUMNS
Inventor: Arthur D. Steffee, Moreland Hills, Ohio
Assignee: Acromed Corporation, Cleveland, Ohio

Appl. No.: 562,438
Filed: Dec. 16, 1983
Int. Cl. A61F 5/04
U.S. Cl. ..... 128/69; 128/92 B
Field of Search ..... 128/92 R

References Cited
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2806414 10/1978 Fed. Rep. of Germany

OTHER PUBLICATIONS

Zimmer, Warsaw, In. 1981 catalog p. B 186.
French Article "Rha natisme Veriebra" (Roy-Camille et al.)

Primary Examiner - Robert Peshock
Assistant Examiner - C.W. Shedd
Attorney, Agent, or Firm - Young & Tarolli

ABSTRACT

An improved apparatus is provided to reduce the extent of displacement between adjacent vertebrae in person's spinal column and to subsequently maintain the vertebrae in a reduced displacement relationship. When the apparatus is to be installed, holes are formed in the displaced vertebra and in vertebrae on opposite sides of the displaced vertebra. Force transmitting members are mounted in the holes in the vertebrae. A spinal plate is then positioned on the spinal column with the force transmitting members extending outwardly through slots in the spinal plate. Nuts are tightened on the force transmitting members connected with vertebrae on opposite sides of the displaced vertebra to anchor the spinal plate in place. A nut on the force transmitting member connected with the displaced vertebra is then tightened to pull the displaced vertebra to a desired position. In one embodiment of the invention, the force transmitting member has a relatively large diameter helix which engages a side wall of the hole in the displaced vertebra. In another embodiment of the invention, an insert is positioned in a hole in the displaced vertebra and expanded by the force transmitting member to securely grip the vertebra.

8 Claims, 14 Drawing Figures * * * *

[Exhibits 3-4 omitted]

EXHIBIT 5

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

September 20, 1985

Food and Drug Administration
Office For Device Evaluations
Document Control Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Variable Screw Placement (VSP)
Spine Plate Fixation System
Number K843600

Dear FDA,

Not withstanding the fact that the Center for Devices and Radiological Health neglected to comply with the 90-day review period set forth in section 510(k) of the Federal Food, Drug and Cosmetic Act, the enclosed clinical data is submitted in response to the Center's letter (copy enclosed) of December 19, 1984, pertaining to your request for additional information in support of our 501K Notification filed on September 12, 1984.

The data specifically addresses your comments regarding a larger sample population, multiple investigators and longer follow up. AcroMed, in its original submission coupled with this supplemental response, has provided information in excess of that required by applicable regulations to meet the criteria necessary to establish substantial equivalency.

The information presented in this submission places K843600 in condition so that the Center is compelled to grant a finding of substantial equivalence. AcroMed respectfully requests that it be notified expeditiously of such a finding. For any further questions, please do not hesitate to contact me.

Sincerely,

/s/
Pamela M. Buckman R.N., M.S.

cc: Ed Wagner, AcroMed
Joe Radzius

PMB/ps
Enclosure: VSP Clinical Report (3 copies)

[Exhibit 6 omitted]

EXHIBIT 7

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

December 20, 1985

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510K Notification

Dear Document Control Clerk:

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the AcroMed Nested Bone Plate is substantially equivalent to devices manufactured and marketed prior to May 29, 1976. We conclude that the following information supports our position.

AcroMed Corporation considers certain information in this document to be of a confidential proprietary nature. Specifically, the engineering drawings and the section headed "description of the device" should not be released through freedom of information act requests or any other way. AcroMed Corporation agrees to notify FDA when there is a change in this status.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
David W. Schlerf

DWS/db
cc: Ed Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

510K PREMARKET NOTIFICATION
AcroMed Nested Bone Plate

NAME OF THE DEVICE:

Trade Name: AcroMed Nested Bone Plate

Common Name: Bone Plates

ESTABLISHMENT REGISTRATION NUMBER:

Number 1526439

CLASSIFICATION:

Bone plates have been classified as Class II medical devices. Performance Standards are applicable.

PERFORMANCE STANDARDS:

To our knowledge, no Performance Standards have been promulgated for bone plates. Until such time as appropriate Performance Standards are developed and published, the manufacturer intends to produce the device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably represent.

LABELING:

Each device will be serial numbered and individually packaged with the following draft label affixed to the package. The labeling will also contain the appropriate cautionary note against intermixing plates and screws of different alloy types.

Proposed Label Sample

AcroMed Nested Bone Plate
316 L stainless steel *

Serial No.: xxxxxx
Contents: One (1)
Size: 160 mm (4 hole)

CAUTION: For sale to or on the order of a physician.

For use in conjunction with plates and screws made of the same alloy

DO NOT MIX DIFFERENT METALS

CLEAN ONLY NOT STERILE

Manufactured For
AcroMed Corporation
2450 Prospect Avenue
Cleveland, OH 44115

* The labeling for the titanium alloy plates will be the same except that this line will indicate "6AL, 4V, TI titanium alloy".

DESCRIPTION OF THE DEVICE:

The AcroMed Nested Bone Plates will be manufactured from 316 L stainless steel surgical implant alloy. This material has been utilized for many years. Additionally, plates made from 6AL, 4V, TI surgical implant titanium alloy are planned. The titanium plates will be introduced according to medical demand and evolving surgical judgement. The physical configuration

and dimensions of the plates will be identical for both alloy types.

The plates will be produced and machined in such fashion that the holes are elongated into "slots" similar to those of the older style "Eggers" plate or the oval elongated slots typical of compression type bone plates. Additionally, each slot has been machined to produce a series of adjacent shallow notches (nests) on the upper slot surface only to allow the appropriate bone screws to seat firmly and securely at the selected location within each slot.

A variety of sizes will be available and defined by descriptors such as 100 mm, 140mm, 160mm or 2, 3, 4 holes, etc. Plates with an additional terminal slot, one half the standard length, will also be available. These plates will be identified by appropriate length in mm and as being 2 1/2 hole, 3 1/2 hole etc. Nominal thickness of both plate alloy types is 4.8 mm.

Serial numbers and sizes as well as the AcroMed Logo will be etched into the finished lateral surface of each plate. This will help positively identify each plate intraoperatively or at such time as the plates might be separated from their packaging materials.

All plate surfaces will be passivated and electropolished. All corners and intersecting surface angles will be radiused. The plates will be stress relieved by an accepted controlled heat, slow cool process. The manufacture of the titanium plates will be likewise except that they will exhibit a "dull" anodized matte finish.

Any required bending, shaping or other modification of the plates necessary to accommodate individual anatomic variations will be accomplished with the use of already approved available orthopaedic instrumentation, bending irons and templates.

Representative graphic examples of the AcroMed Nested Bone Plate are included as engineering drawings in Exhibit I.

INSTRUMENTATION:

No special instrumentation is required. The AcroMed Nested Bone Plate has been designed to utilize existing general orthopaedic instrumentation for their insertion and/or modification.

SUBSTANTIAL EQUIVALENCE:

Other than the "multiple nesting" of the slots, there is no new application, indication, material, device configuration or specification presented here. The AcroMed Nested Bone Plate is substantially equivalent to many current and preammendment devices intended for use in orthopaedic fixation and stabilization of osseous fractures.

Such preammendment and substantially equivalent devices include, but are not limited to: The Modified Eggers bone plate, A O (DCP) bone plates, Synthes bone plates, ASIF bone plates, Smith Kline Surgical Specialties bone plates and bone plates manufactured by King Manufacturing, DePuy, Richards Medical Company and Zimmer USA as well as many lesser known companys. The use of titanium as a preammendment implant alloy is established by the Zimmer USA/Coonrad total elbow and the Thompson Corporation titanium wrist fusion implant. The Ace Medical Company marketed a similar "slotted" titanium bone plate with a single "nest" in the center of each slot several years ago. The Ace device was approved via the 510K process. Exhibit II contains preammendment device references.

[Exhibits to 510(k) Premarket Notification omitted]

EXHIBIT 8

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

December 30, 1985

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510K Notification

Dear Document Control Clerk:

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the AcroMed Cancellous Bone Screw is substantially equivalent to devices manufactured and marketed prior to May 28, 1976. We conclude that the following information supports our position.

AcroMed Corporation considers certain information in this document to be of a confidential proprietary nature. Specifically, the engineering drawings and the section headed "description of the device" should not be released through freedom of information act requests or any other way. AcroMed Corporation agrees to notify FDA when there is a change in this status.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
David W. Schlerf

DWS/db
cc: Ed Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

510K PREMARKET NOTIFICATION
AcroMed Cancellous Bone Screw

NAME OF THE DEVICE:

Trade Name: AcroMed Cancellous Bone Screw
Common Name: Bone screws

ESTABLISHMENT REGISTRATION NUMBER:

Number 1526439

CLASSIFICATION:

Bone screws have been classified as Class II medical devices. Performance Standards are applicable.

PERFORMANCE STANDARDS:

To our knowledge, no Performance Standards have been promulgated for bone screws. Until such time as appropriate performance standards are developed and published, the manufacturer intends to produce the device in accordance with the regulations and standards that are appropriate to the risk that Class II devices reasonably represent.

LABELING:

Each device will be individually packaged and lot numbered with the following draft label affixed to the package. AcroMed also intends to produce, package and sell the screws in multi packs such as 2, 3, 4, etc. of the same or assorted size screws per package. Inasmuch as AcroMed intends to produce both stainless steel and titanium screws, an appropriate warning against intermixing screws and plates of dissimilar metals will be included.

Proposed Label Sample

AcroMed Cancellous Bone Screws
316 L stainless steel *

Serial No.: xxxxxx
Contents: One (1)
Size: Length 160 mm
Diameter 6.62 mm

CAUTION: For sale to or on the order of a physician.

For use in conjunction with plates and screws made of the same alloy

DO NOT MIX DIFFERENT METALS

CLEAN ONLY NOT STERILE

Manufactured For
AcroMed Corporation
2450 Prospect Avenue
Cleveland, OH 44115

* The labeling for the titanium alloy screws will be the same except that this line will indicate "6AL, 4V, TI titanium alloy".

DESCRIPTION OF THE DEVICE:

The AcroMed Cancellous Bone Screws will be manufactured from 316 L stainless steel surgical implant alloy. Additionally, screws made from 6AL, 4V, TI surgical implant titanium alloy are planned. The titanium screws will be introduced according to medical demand and evolving surgical judgement.

The screws will be produced and machined in such fashion that they will exhibit the general physical configuration of a "Hagie-type" pin, including the removable hex nuts. The shaft of each pin has been manufactured with a hex drive and section to facilitate insertion. A variety of sizes will be available, such as, 30 mm through 160 mm in 2-4 mm increments. Initially, three different pin diameters will be offered for each available length. At present, screws with major cancellous diameters of 5.5mm, 6.5mm and 7.0mm are planned. Major machine screw diameter of the pin shaft will be 4.75 mm and of 10/32 pitch. Additional sizes will be added based on medical demand.

The 3/8" hex nuts are drilled and tapped to accommodate the 10/32 machine thread on the 4.75 mm shaft of the screws. Hex nuts of different sizes will be added to accommodate the above changes in pin shaft diameter at the appropriate times.

Each screw will have either an "S" or "T"etched into the finished hex drive surface of each screw shaft. Each hex nut will be likewise identified. This will help to positively identify the screw/nut alloy types intraoperatively or at such time as the screws might be separated from their packaging materials.

All screw and hex nut surfaces will be smooth and polished. All corners and intersecting angles will be radiused. The manufacture of the titanium screws and nuts will be the same.

Representative deminsions and configuration of the AcroMed Cancellous Bone Screws are included as engineering drawings in Exhibit I.

INSTRUMENTATION:

Instrumentation is required to insert and anchor the AcroMed Cancellous Bone Screws and hex nuts. The screws/nuts have been designed to utilize general orthopaedic instrumentation of the appropriate size and configuration.

SUBSTANTIAL EQUIVALENCE:

There is no new application, indication, material, device configuration or specification presented here. The AcroMed Bone Screw is substantially equivalent to many current and preammendment devices intended for use in orthopaedic fixation and stabilization of osseous fractures where metalic screws or plates and screws are indicated.

Such preammendment and substantially equivalent devices include, but are not limited to: The A O System of cancellous bone screws and cancellous bone screws such as those produced by King Manufacturing, DePuy and Zimmer USA as well as many lessen known companys. DePuy and Zimmer USA also produced the previously mentioned preammendment "Hagie-type" pins.

The use of titanium as a preammendment implant alloy is clearly established by the Zimmer USA/Coonrad total elbow and the Sampson Corporations titanium wrist fusion implant. Ace Medical Company also marketed and sold a titanium bone screw and plate that was approved via the 510K process. Examples of substantially equivalent devices are included in Exhibit II).

[Exhibits to 510(k) Premarket Notification omitted]

EXHIBIT 9

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94533
(415) 372-7740

January 10, 1986

Kenneth McDermott
Food and Drug Administration

Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Re: K#855224
AcroMed Nested Bone Plate

Dear Kenneth:

Thank you for your prompt attention to this matter. This letter is sent in response to your telephone request for additional information. If I understood you correctly, the only area of concern you addressed was the need for a more definitive statement covering the intended "indications for use" of the AcroMed Nested Bone Plate.

The proposed indications for use for the AcroMed device are the same general indications proposed for the AO system of plates. More specifically, (for the purpose of this 510K), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis) that may from time to time require stabilization with contourable metallic non-compressing plates.

Kenneth, I hope that the above statements provide you with the information necessary to allow for the timely approval of this submission. In the event that you still require additional information, please do not hesitate to call me at (415) 372-7740.

In closing, allow me to again thank you for your courtesy and promptness in reviewing this 510K Notifcation.

Sincerely,

/s/
David W. Schlerf

SWD/cb
cc: Edward Wagner, President, AcroMed Corporation

EXHIBIT 10

[Feb 18 RECD]

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: K860017 AcroMed Cancellous Bone Screw

Mr. David W. Schlerf
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dated: December 30 and 31, 1985
Received: January 3, 1986

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the

misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,
/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

[Feb 18 RECD]

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: K855224
AcroMed Nested Bone Plate

Mr. David W. Schlerf
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dated: January 10, 1986
Received: January 17, 1986

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future,

the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

EXHIBIT 11
INVESTIGATIONAL DEVICE EXEMPTION
VARIABLE SCREW PLACEMENT (VSP) SYSTEM
FOR
SPINAL APPLICATIONS

Sponsored by
ACROMED CORPORATION
CLEVELAND, OHIO

Submitted by Buckman Company, Inc.
January 17, 1986

*** PURPOSE OF THE STUDY: The purpose of the study is to provide evidence that supports the use of the VSP Spine Plate System to achieve stability in the adult spine. Surgical use of the system is primarily intended to achieve the following clinical results:

1. Reduction in pain.
2. Increase in function

RATIONALE: In the past attempts at stabilizing back surgery have involved two stage procedures: a posterior procedure followed by an anterior operation approximately two weeks later. The double jeopardy type of surgery requires two excursions under anesthesia, and a longer, more difficult recovery. The fact that spine plate surgery is a one-stage, posterior approach eliminates these obvious disadvantages. A second consideration is that in the past most efforts to stabilize an unstable spine involved a distraction method of correction. This straightens the spine, giving the patient a forward tilt, ie., loss of lordosis, which in turn disrupts balance, gait and posture.

The newly designed spine plates, by comparison, can be easily bent in surgery to conform to, or create, the patient's lordotic curve.

Maintenance of either a lordosis or thoracic curve is essential to good mobility and balance following surgery.

Another advantage to spine plating was the immediate, solid fixation could be achieved. No other form of bracing, casting or any other type of immobilization would be required. The patient could then be expected to ambulate more quickly both with and without assistance. Furthermore, the elimination of immobilization would prevent the hazards associated with stress deprivation, which hinders the patient's recovery. The hospital stay could thereby be reduced when compared to other comparable types of back surgery.

NOTE: Rationale section above provided by Arthur Steffee, M.D., Primary Investigator for the Study

INDICATIONS FOR USE: The VSP Spine Plate System will be studied in patients with any condition of the spine resulting in instability. The specific diagnoses may include the following:

1. Degenerative, true and traumatic spondylolistheses
2. Traumatic or pathological fractures
3. Failed back syndrome
4. Pseudoarthrosis
5. Instrumentation failure
6. Tumors
7. Adult degenerative and paralytic scoliosis
8. Degenerative disc disease

SAMPLES AND POPULATION: The study subjects will number 200 to 250 adult patients. Subjects will be entered from multiple test sites. A minimum of three institutions from three different geographical locations has been established. The study will be expanded to other locations as Orthopaedic Surgeons agree to the protocol and obtain Institutional Review Board approval. * * * *

EXHIBIT 12

AcroMed Corporation
2450 Prospect Avenue
Cleveland, Ohio 44115
216/771-5800

January 16, 1986

Michael R. Zindrick, M.D.
Hinsdale Orethopedic Associates, S.C.
550 North Monroe Street
Hinsdale, IL 605221

Dear Dr. Zindrick:

Belated though it is, my thanks for sending a copy of the AO manual on spinal plate fixation. Unfortunately, the manual's second edition is dated 1979, which is three years too late to establish a pre May, 1976 use for a reference for our plates and screws. I was able to locate a copy of the first edition (1969), but there was no appropriate reference. Without an applicable citation, we have prepared and today sent an IDE for the VSP Spine Plates and Screws to FDA.

In the meantime and until the IDE is completed, we have acceded to FDA's position that we refer to the plates as "bone plates" and the screws as "bone screws," a labeling slight-of-hand that satisfies the agency's regulations but in no way changes the intended use of the plates and screws. As one of the FDA staffers commented, bones are bones, and it is the judgment of the surgeon that controls the use of the implants.

See you in New Orleans.

Sincerely yours,

/s/

Edward J. Wagner
President

EJW:sh

[Exhibit 13 omitted]

EXHIBIT 14
MEMORANDUM OF INTERVIEW
WITH ROBERT A. TAYLOR

Robert A. Taylor
7560 Hollycroft Apt. E5
Mentor, Ohio
(216) 255-4437

At about 6:30 pm, accompanied by R. M. Koeninger, I visited Mr. Taylor and interviewed him regarding his knowledge of events which occurred while he was employed by Acromed Corp., 3303 Carnegie Ave., Cleveland, Ohio.

Mr. Taylor came to work at Acromed in the fall of 1984. He was to implement a quality control and GMP program and become V.P. of Operations. As V.P. of Operations, he had little to do with sales of products made/sold by or for Acromed. His was primarily the acquisition, design and quality aspects of the operation. He said that Ed Wagner initially put together the Catalog.

He knew that in late 1985 that a lawyer, (later identified as Joe Radzius), Ed Wagner, Dr. Steffee and possibly Pam Buckman went to visit Medical Devices personnel to see if there was not some way to put the devices into the market. He overheard discussions in which the participants and to meetings with CDRH had said they were told how to put their devices in the market, i.e. as bone plates. Then to study the devices for use in the spine as spine plates and

pedicle screws. They were for spine use. He said they spent a lot of money on research with the various doctors to get the plates and screws approved for spine use. He said promotion was done by word of mouth, at conventions and by referring doctors who were not on the list of approved customers to Dr. Steffee for training. They would not sell to anyone not trained by Steffee or by a Steffee associate because Acromed and Steffee did not want VSP plates to be improperly used.

As part of his job, Taylor would take the calls referred to him by customer service if they had a problem customer. He cited one example of a Cleveland area doctor who demanded that the plates and screws be sent to him immediately because he intended to do plate implantation the following day. The policy of refusing to ship to an unapproved customer was upheld by customer service and when the doctor became furious and abusive he was referred to Taylor who said he steadfastly held to Acromed's policy of not shipping VSP systems to unapproved customers. Koeninger asked him, "What if the doctor had represented that he wanted to use the device in an arm or leg, would you (Acromed) have shipped them?" Mr. Taylor responded that he would not have approved the shipment even for that use unless the doctor had "scrubbed" with Dr. Steffee and was approved.

Harriet Foster was the senior customer service person who received orders and made initial checks into customer "approved status".

Taylor said he had heard that one or two VSP plates had been tried on long bones, but he was not sure it was true.

Taylor was not aware of how many sets of plates and screws had been sold, but said there were "thousands and thousands of sets of plates shipped."

Taylor was asked about the clamps and if they were approved. He said they were not, but were dropped primarily because they were

not as effective as had been hoped. He said they had shipped the plastic pedicle spacer to doctors and had tried to market the device as a "Custom" device, but stopped after notice from FDA. He said the device was one which had to be on hand before surgery began because the need for it was never certain until the surgeon got into the back.

We asked Taylor how he handled complaints about screws that failed or "broken screws". His response was that even though the screw broke, the patient might have had a complete fusion and the back would be repaired. This was not considered a failure of the device. He said they rarely ever received notice from hospitals or surgeons that the screws had failed or broke at Acromed's Corporate offices. He said these reports usually were made first hand by the surgeon at the display booths at the conventions. This reporting was handled by referring the physician to Dr. Steffee who usually attended the conferences and manned the booths part of the time. They would simply tell the doctor, "Dr. Steffee will be here about 2:00 pm, please come back then and he will be able to help you, that is not our area of expertise".

Taylor said he sat in on many "idea" meetings where doctors, "who are all inventors", proposed ideas and the design folks would evaluate it. Some, maybe a few percent, were thought to be worthy of any serious follow-up after only cursory review of engineers. Some had been developed.

Taylor said persons (doctors) fully interested in use of VSP system were referred to Steffee for training. He said that Steffee had done training at several locations in the United States when sufficient candidates were present. Steffee might also scrub with the doctor if he was in the area for some other purpose.

Taylor said Acromed had originally had a small clientele of approved customers who would be able to schedule surgeries early

enough to order the needed devices from Cleveland and not maintain large inventories. He said that Dr. Brown, Human Hospital in Miami had a practice where he did numerous trauma repairs and that his brother, Tony Brown, had become the first Acromed dealer. He maintained a stock of devices for emergency use and later provided devices to other surgeons. Taylor thought the approved doctor list was maintained by the dealers also. Since the first dealer, several had been established.

The new president of Acromed is the owner of the Dutch subsidiary of Acromed, Ortomed. Taylor had gone to Holland to oversee GMP setup and advise on the production requirements for the VSP system there. Acromed purchased the stainless steel and shipped it to Ortomed for use in producing VSP. All the VSP system components made by Ortomed are sold in Europe. None are imported into U.S.A.

Subsequent to our initial discussion of these facts, Farr revisisted the issue of controlling the sales to exclude all except those who knew how to use it in the spine. Taylor said the device was always intended for use in the spine and was never distributed to parties who were not known to have the skills and training to implant in the spine. Complaints were voiced at the booth at conventions by doctors, but rarely reported to the firm directly. Farr asked against about how the product was promoted and was told, generally referrals, word of mouth, medical article generated journal entry inquiries and then referral to Steffee for training.

Taylor encountered Buckman and Associates as part of their studies. He said a lot of money was being spent on the studies. Taylor said Buckman is no longer doing the studies, only consulting and using the study data base developed by Buckman on VSP.

We thanked Mr. Taylor for the cooperation and told him that he would likely be visited again in the future as the investigation progresses.

/s/
Leonard J. Farr

[Exhibits 15-18 omitted]

EXHIBIT 19

* * *

DEPARTMENT OF HEALTH & HUMAN SERVICES

[Handwritten: 12/22/89 [illegible] 00204 [illegible] Greensboro RP Please visit 2 NC Hospitals within the next 2 weeks and get info requested by CinDO]

Date: December 18, 1989

From: L.J. Farr Compliance Officer
Clinical District

Subject: Investigation Request — Arthur Steffee, MD
Acromed Inc.
Cleveland, Ohio

To: Director of Investigations
Branch, Atlanta District

Variable Screw Placement (VSP)
Bone Plates and Screws

Hospitals: Durham County
General Hospital
Durham, N.C.

Duke University
Durham, N.C.

Following an ad hoc meeting with CDRH, OE and GCF-1, CinDO is developing evidence to support an injunction and needs assistance in the form of a prompt and detailed investigation as is requested below. Facts in hand show that Arthur Steffee, MD, an orthopedic surgeon, has developed several spinal implant devices for use in stabilizing the spine for various injuries and with fusion surgeries. These are marketed though Acromed, Inc. In 1985, the AcroMed, Inc. firm, through its monitor firm – the Buckman Company of Martinez, Calif. submitted a 510K for The Variable Screw Placement (VSP) Spinal Fixation System which included stainless steel slotted plates, washers and screws for the purpose of implanting with intended use in spinal fixation. The firm was told this was not a Class II device as it was not substantially equivalent to any existing device or pre-amendment device and that 501K would not suffice, but that on IDE and subsequent PMA would be required for marketing the device system for spinal fixation surgery.

The firm subsequently met with CDRH's Office of Device Evaluation. This meeting resulted in the firm recognizing that the parts of its system could be 510K approved as equivalent (substantially) to other devices and that FDA could not prohibit surgeons from using the devices as they chose. The firm submitted 510Ks for parts of the devices, plates screws, washers separately. The declared use of the plates in the 510K was for long bones of the upper and lower extremities and flat bones such as the pelvis. The firm was warned against promoting the devices for use in spinal surgery.

Subsequently the firm set about submitting an IDE and called its devices in the IDE "Variable Screw Placement Spinal Fixation Plates (VSP) and Transpedicular Screws". Several physicians have conducted studies on this sytem. However, the firm has marketed many thousands of the VSP plates and screws to hospitals and surgeons for use in spinal fixation surgery without sanction of the

Investigational Device Exemption by providing the intended use through seminars, training, publication, and word of mouth recommendations by surgeons who were involved in the IDE work.

* * * *

[Exhibits 20-22 omitted]

EXHIBIT 23

Department of Health and Human Services
Public Health Service
Food and Drug Administration

District Address and Phone Number:
1141 Central Parkway
Cincinnati, OH 45202
(513) 684-3501

Date of Inspection: 7/14, 17-20, 25-27 & 8/17/89

Type Establishment Inspected: IDE Study Sponsor

Firm Name: AcroMed Corporation

Name of Firm, Branch or Unit Inspected: same

Street Address: 3303 Carnegie Avenue

Street Address of Premises Inspected: same

City and State: Cleveland, OH 4415

City and State: same

During an inspection of your firm, (I) (we) observed:

IDE G860013 involved the use of VSP Spine Plates, VSP Transpedicular Screws and VSP Plate Clamps for spine stabilization. The

plates and screws were the same as plates and screws being marketed as VSP Bone Plates and VSP Bone Screws.

* * *

5. COMMERCIALIZATION
   a. During the time of the IDE studies and after they ended, bone plates and bone screws were sold to hospitals for spinal use by non IDE physicians. IDE Spine Plates were sold to St. Vincent Charity Hosp. after Dr. Steffee's last subject. Doctors (IDE and nonIDE) were trained how to perform the operation by Dr. Steffee (Chairman of the Board of AcroMed). Data for these nonIDE patients have been collected on the same patient information forms used during the IDE study.
   b. VSP Plate Clamps [handwritten: buttress clamps] were sold to non IDE hospitals during the IDE study and to Non IDE and IDE hospitals after the study.
   c. AcroMed has distributed video tapes and VSP Plating System Technique Manuals showing spinal use of these plates and screws. [Handwritten: ?promotion]

Employee(s) Signature: /s/
Employee(s) name and title: Frederick M. Lochner, Investigator

EXHIBIT 24

Department of Health and Human Services
Public Health Service
Food and Drug Administration

District Address and Phone Number:
1141 Central Parkway
Cincinnati, OH 45202
(513) 684-3501

Name of individual to whom report issued: Dr. Arthur D. Steffee

Date of inspection: 6/22, 23, 26-28, 7/6, 13, 21, 8/22, 29/89

Type of individual: M.D.

Type establishment inspected: Clinical Investigator

Firm name: Arthur D. Steffee, Inc.

Name of firm, branch or unit inspected: same

Street address: 2709 Franklin Blvd.

Street address of premises inspected: same

City and state: Cleveland, OH 44113

City and state: same

During an inspection of your firm, (I) observed:

IDE G860013 involved the use of VSP Spine Plates, VSP Transpedicular Screws and VSP Plate Clamps for spine stabilization. The plates and screws were the same as plates and screws being marketed as VSP Bone Plates and VSP Bone Screws.

* * *

4. Dr. Steffee trained both IDE and non IDE doctors how to use the plates, screws, and clamps for spine stabilization. He and/or people in his office prepared materials (video tapes, booklet, technique manual) showing the use of these devices for spinal use.

Employee(s) signature: /s/
Employee(s) name and title: Frederick M. Lochner, Investigator

EXHIBIT 25

CONFIDENTIAL
SUBJECTIVE TO PROTECTIVE ORDER

III. SITUATION ANALYSIS

The following narrative of the current market situation provides an assessment of competition and competitive activities, market trends, changes in technology, the regulatory environment, our products, our customer service, physical distribution and service levels, our distributors, and our customers' attitudes toward the company.

VSP System

The overriding marketing consideration for VSP Plates and Screws in FY 90 has been the regulatory environment. The FDA has increasingly brought pressure on AcroMed (as well as its competitors), AcroMed's customers and its distributors to insure that these products were not being promoted for non-indicated uses.

As a result, we have had to be extremely circumspect in our approach to surgeons. We continue to maintain a posture of marketing Bone Plates and Bone Screws, while continuing our responsibility of providing information and educational avenues for surgeons who choose to use these products for spinal fixation.

We have used a variety of educational vehicles to this end. The most productive of these have been Institutional-sponsored seminars on pedicle fixation, regional and national professional meeting which include a laboratory or workshop on pedicle fixation, and a visiting surgeon program with the Cleveland Spine and Arthritis Center of two to three days to observe implantation techniques of these devices. We have maintained a low profile by not sponsoring or officially participating in these forums except as exhibitors where appropriate.

We have also continued to enforce our policy of not selling to any surgeon who has not attended a VSP seminar, scrubbed in with an experienced VSP user, or who does not have significant experience with pedicle fixation using other systems. * * * *

[Exhibits 26-27 omitted]

EXHIBIT 28

AcroMed Corporation
2450 Prospect Avenue
Cleveland, Ohio 44115
216/771-5800

CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER

April 18, 1986

Tony Brown
R.A. Brown & Associates
7800 Red Road
Suite 304
Miami, FL 33134

Dear Tony:

With reference to our telephone conversation on April 14 about your participation in assisting us in developing a comprehensive marketing program for our existing and projected products, I want to take this opportunity to outline our thoughts as they exist at this time about the scope and direction of the program. The information furnished to you is regarded by us as confidential and proprietary and therefore is not to be shared in whole or in part with any other person.

By way of background . . . we are selling our VSP Bone Plates and VSP Bone Screws without a formal marketing program, indeed without any marketing or sales staff and without any advertising. Dr. Steffee has "promoted" the device with other surgeons through word-of-mouth, technical exhibits, published papers, educational conferences and the like. This approach has been assisted and reinforced by informal endorsements by other surgeons. In two years plus it has proven to be reasonably effective. Pending completion of the IDE/PMA and FDA's approval, we cannot yet

state explicitly that the plates and screws are for use specifically in the spine: In the meantime we are restricted to calling them "Bone" Plates and Screws, though they can be used in thge spine. I expect we will complete the PMA in about 36-40 months. * * * *

[Exhibits 29-47 omitted]

EXHIBIT 48

DATE: 9/11/91

TO: Donald F. Fernholz
SCSO, BRN-RP

FIRM: AcroMed Corp.
Cleveland, OH

SUBJECT: Investigation

Paula Ames
13400 Shaker Blvd.
Cleveland, OH
216-283-5571

FROM: Frederick M. Lochner
Investigator

Per verbal instructions from CIN-DO Compliance Officer Leonard Farr, I interviewed Paula Ames at her home on 9/10/91. I was accompanied by Investigator Susan C. Morgan. The interview involved activities at AcroMed Corp.

Ms. Ames no longer works at AcroMed. She was hired about October 1987 and fired about April 1988. She was the Director of Business Development. She said Ed Wagner fired her because he felt she was trying to take over the company. Most of her time was spent learning the firm's operations but she was involved with marketing and advertising of the firms products. Ed Wagner was her boss. Dr. Steffee did not come around the office very often. Ed Wagner was in charge of the operation of AcroMed.

* * * We discussed the booths AcroMed had at orthopedic conventions and seminars. Ms. Ames was one of the people

working at the booths. She said she was in training so did not deal with the people who came to the booths very much but did hand out materials that AcroMed provided to be passed out. Mr. Watermeier was the main spokesperson at the booths. Ms. Ames said he was in charge of the literature and materials available at the booth but Ed Wagner gave the orders as to what would be available and how it would be distributed. Mr. Taylor and other AcroMed people would also take turns at the booths. AcroMed took part in these conventions (bought the booth space) but did not sponsor the conventions.

Ms. Ames stated videotapes were available at the booths both for viewing and distribution. I showed her the titles of two videos ("The VSP System" and "Pedicular Fixation with VSP Plates"). She recognized them and thought they were the ones available at the booths. She did not remember a Technique Manual being available. I also showed her a series of reprints of journal articles. She said they looked like what was also available for distribution at the booths. She said they had a lot of material to hand out.

I asked if any of these handouts were stamped or marked to indicate the plates and screws were investigational devices if for use in the spine. She did not remember if such stamps were used or not. She said there was no doubt the plates and screws were for spine use. They never were intended for use on arms or legs.

Ms. Ames said they knew the plates and screws had not been approved for spine use. Mr. Watermeier was very aware of this. He stressed caution when promotion for spine use was involved. He was very nervous about using the videos. Ed Wagner was not nearly as cautious and pushed the distribution of the literature and use of the videotapes. He was ultimately responsible for the promotional materials used according to Ms. Ames.

We also discussed the seminars/training sessions where surgeons were taught how to implant the plates and screws on spines. Ms. Ames said she would sit in at these sessions to observe. Dr. Steffee would give lectures using slides and films and doctors would actually implant the devices. Literature and videos were also available to participants. She was not sure of AcroMed's actual involvement with the training sessions including if AcroMed sponsored or paid for them. She did not know where and when each was held.

* * * Ms. Ames said there was no doubt AcroMed was promoting and marketing the plates and screws for spine use. The employees knew they had not received approval for this use and were surprised not only about the prices charged but the large amount of sales. She said some people at AcroMed desired a conservative approach and were concerned about the legality of the promotional activities. These included Mr. Watermeier, Mr. Taylor and Terry (the engineer). Mr. Wagner preferred a more active approach and pushed the employees to actively promote the VSP system for spine use. He had the ultimate decision on how active the promotions would be. At times Mr. Watermeier would argue with Mr. Wagner over the distribution of the videos but Mr. Wagner controlled this and had the final say. Mr. Watermeier would try to put reins on the promotional activities but Mr. Wagner would go ahead and do whatever he wanted. * * * *

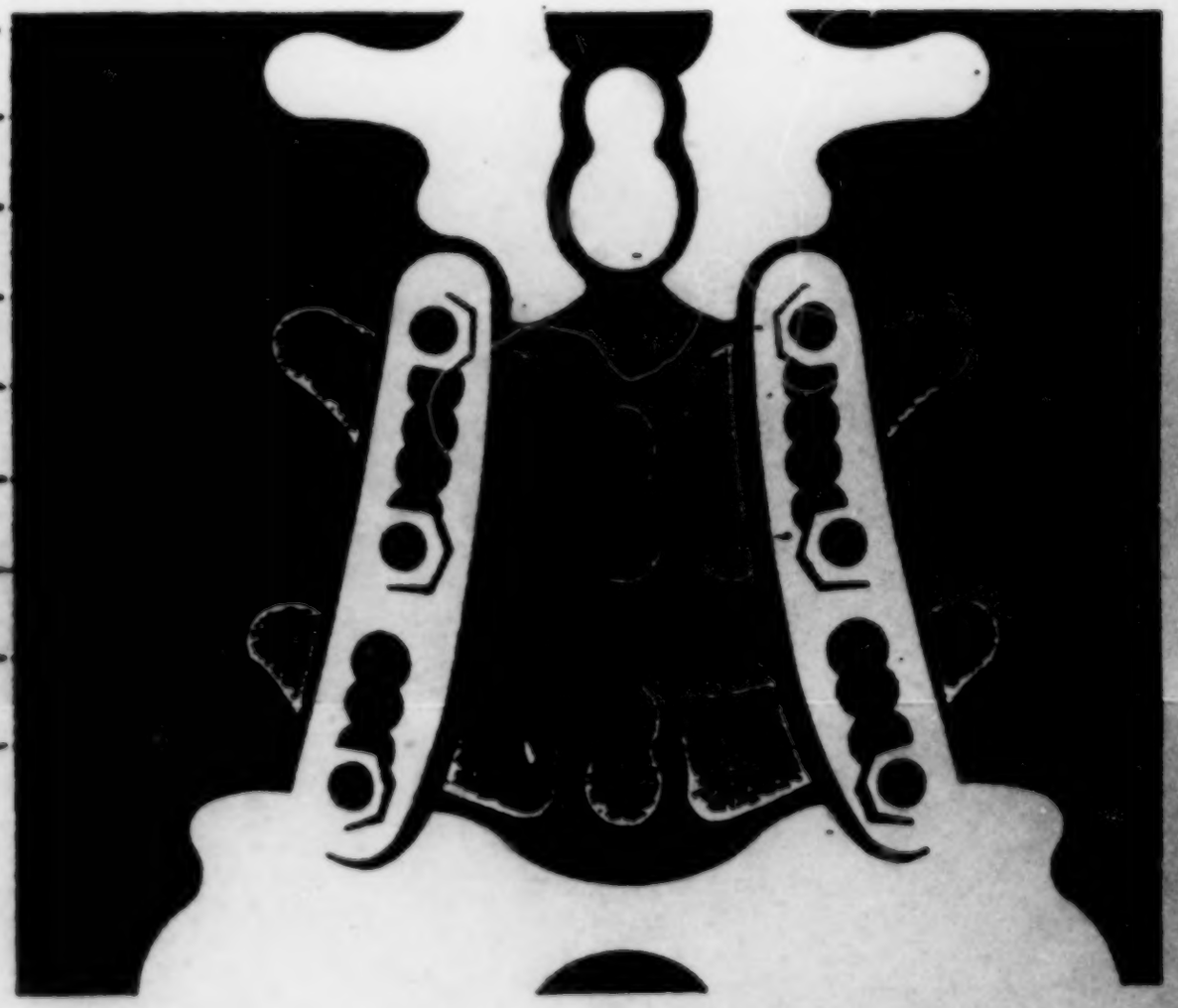
EXHIBIT 49

[See following inserted pages, which are redacted portions of exhibit]

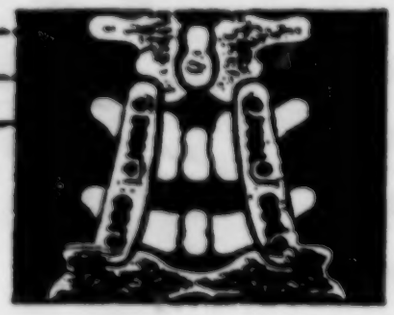
BEST AVAILABLE COPY

Assgn. FD-189
Roger M. Sobel, M.D.
1-24-90 TA/DLB
Exhibit 3.1

VSP Plating System Technique Manual



Assgn. FO-10a
Roger M. Sobel, M.D.
1-24-90 TA/DLB
Exhibit E.7.



Dear Colleague,

After attending a number of seminars, courses and scientific meetings that have dealt with the use of plates and screws for spinal alignment and stabilization, and after discussing with other surgeons who, like ourselves, have had some experience with these devices, we believe it would be helpful to set out some techniques and guidelines that we have found successful in our own surgical practices when we use such devices.

The contents of this manual are not adequate for complete instruction in the use of this system. Only a qualified surgeon who is skilled in spinal instrumentation and understands the biomechanics of the unstable spine should use this system. Lack of expertise in surgical stabilization of the unstable spine may result in avoidable complications.

Like everything else, these devices are not meant to address every spine related problem, rather they must be used with a great degree of care and skill, and must be buttressed by sound diagnostics and skillful aftercare.

It is our hope that this manual will be helpful as you develop your skill to the point that these plates and screws will become a regular part of your surgical armamentarium.

Arthur D. Steffee, M.D.
Cleveland, Ohio

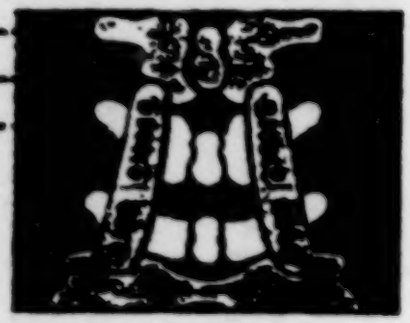
Louis Keppler, M.D.
Cleveland, Ohio

Roger A. Sobel, M.D.
1-24-90 TA/DLB
Exhibit

BACKGROUND

The VSP (Variable Screw Placement) Bone Plate and Bone Screw System may be used by surgeons to address any number of surgical situations (see primary indications) and was developed with an understanding of the concept of the "force nucleus" as an explanation of the dynamics of the forces and elements that interact to bring balance, form and structure. Applying this concept to the spine, it was determined that each motion segment has "two "force nuclei," through which five anatomical structures: the superior facet, the inferior facet via the pars interarticularis, the lamina, the pedicle and the transverse process, channel all posterior forces that are transmitted to the body.

The "force nucleus" of normal vertebrae is located at a point where the ridge of the pars, the ridge of the superior facet and the ridge of the transverse process converge (Fig. 1) Opening the cortical bone at this point offers the "force nucleus" a "window" into the intramedullary canal of the pedicle through which the screw passes into the body of the vertebra. (Fig. 2)



FORCE NUCLEUS OF VERTEBRAE

Fig. 1

Fig. 2

PRIMARY INDICATIONS

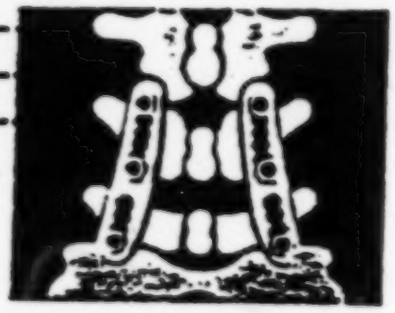
Use of the screws and plates are indicated in situations of spinal instability,* including:

- Spinal Trauma, including fractures
- Degenerative Spondylolisthesis
- Isthmus Spondylolisthesis
- Vertebral Body Arthroplasty
- Degenerative Disc Disease
- Adult Onset Scoliosis
- Paralytic Scoliosis
- Fixation of Vertebral Osteotomy
- Acquired Instability
- Tumors

Roger A. Sobel, M.D.
1-24-90 TA/DLB
Exhibit

CONTRAINDICATIONS

- History of Infection
- Bony abnormalities preventing safe screw fixation (dysplastic pedicles)
- Patients who have been shown to be safely and predictably handled without internal fixation
- Morbid Obesity
- Severe Osteopenic
- Open Wounds
- Metal Sensitivity
- Rigid Scoliotic Curves



SYSTEM COMPONENTS:

BONE SCREWS

The VSP Bone Screws are fabricated from 22-13-5 stainless steel, and are composed of two parts a long cancellous section with an integral fixed lower nut, and a machine threaded section topped with an hexagonal drive head.

The screws and plates are coloned utilizing a double nut locking system. The screw features an integral fixed lower nut that is machined directly from the same piece of metal stock. (Fig. 3)

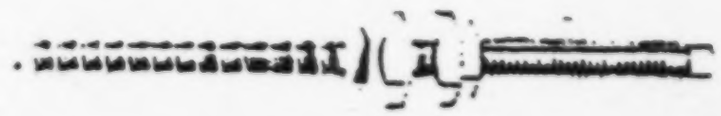


Fig. 3

IMPLANTABLE PLATES

The VSP Bone Plates are fabricated from 316 LVM implant grade stainless steel. The plates have nested slots and variable lengths to span the vertebral levels to be stabilized. The plates have between one to five slots. (44 mm to 196 mm length) with their length increasing by half slot increments. Longer plates are available as special order items.

The slots, with their precisely machined tapered nests, offer the possibility of accurate yet variable screw placement along the spinal column. It is important that the plates be bent in a plate bender to mirror or to create the desired sagittal curve of the spine.

Use the shortest plate possible for each procedure. Minimal plate length will reduce the possibility of plate interference with any uninvolved facet joints. (Fig. 4)

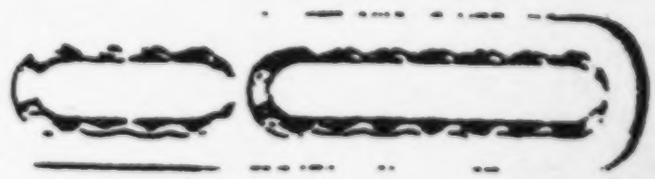


Fig. 4

BEST AVAILABLE COPY

[Exhibits 50-51 omitted]

EXHIBIT 52

AcroMed Corporation
3303 Carnegie Ave.
Cleveland, Ohio 44115
216/431-9900

TO: Physicians Utilizing VSP Bone Plates and Screw System
FROM: AcroMed Corporation
DATE: September 1, 1987
RE: Patient Consent Form

We have been asked over the past several months by a number of surgeons for information about a Patient Consent Form for use when performing procedures utilizing various spinal implant devices. It occurred to us that others may be asking the same question.

As a courtesy service, we have asked our legal counsel to draft an appropriate consent form, and he has produced the enclosed draft.

You may want to compare the Patient Consent Form you are now using and determine which may be better, i.e., adopt only some of the language and terms, delete others, but make as certain as possible that you have the best form you can. As you are aware, informed consent by a patient entails more than just signing a form. The items in the consent form must be discussed with and explained thoroughly to the patient in order for the consent to be effective.

Since we are not in the business of providing legal advice, the enclosed draft is offered to you without recommendation, but as a courtesy to share information that you and your legal counsel may find helpful.

Edward J. Wagner
President & CEO

[Exhibits 53-84 omitted]

EXHIBIT 85
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

SUPPLEMENTAL DECLARATION OF
CARL A. LARSON, PH.D.

I hereby declare:

1. My duties as Director of the Office of Surgical and Rehabilitation Devices from October of 1979 through January of 1992 included supervising the evaluation of devices submitted for 510(k) substantial equivalence determination as well as Pre-Market Approval evaluations.

2. When a device manufacturer submits a device for a 510(k) substantial equivalence determination, the only thing the device is reviewed for by the FDA reviewers is for its "substantial equivalence" to a device with the same intended use and substantially similar technological characteristics (design and materials) and application to a device in use prior to adoption of the Medical Device Amendments. As set forth more fully in my Declaration of November 26, 1994, the Medical Device Amendments came into effect in 1976.

3. The 510(k) notification process only provides for the FDA to review the submitted devices to determine whether they are "substantially equivalent" to existing devices, which means equivalent in intended use and technological characteristics and, further that the device does not raise new safety and effectiveness questions for its intended use.

4. In reviewing a 510(k) submission, the FDA does not make any determinations whatsoever relating to the sufficiency of labeling nor the safety and effectiveness of the submitted device. Although proposed labeling and often times test results are submitted with the 510(k) application, they are not evaluated for their sufficiency or for the device's safety and effectiveness.

5. The FDA did make a determination in November of 1985 that AcroMeds VSP Pedicle Screw device was not substantially equivalent to a pre-amendment device for use in the pedicles of the spine and, therefore, as a Class III significant risk investigational device, required proof of its safety and effectiveness through the Pre-market Approval (PMA) Process.

6. The manner in which Class III devices, such as pedicle screws, are reviewed for determinations of safety and effectiveness and sufficiency of labeling is through the PMA Process. As part of the PMA process, the FDA comprehensively evaluates the device, the sufficiency of its labeling and the safety and effectiveness of the device through detailed prospective clinical trials which are closely monitored and evaluated by the FDA both during and after the actual trials are conducted. Not only is AcroMed's VSP device for use in the pedicles of the spine a Class III significant risk investigational device, it is also considered a critical device by the FDA. A critical device requires even greater GMP controls and tracking procedures than other Class III devices. (See Scarlett Affidavit paragraphs 62-64, attached as an exhibit to AcroMed's Brief).

7. AcroMed then reapplied for 510(k) substantial equivalence determination for certain limited components of its previously submitted VSP device and disengenuously indicated to the FDA its use as a fixation device for fractures of long bones, a Class II moderate risk use (See Declaration of Carl Larson, November 26, 1994 paragraphs 41-43).

8. A 510(k) substantial equivalence determination is not tantamount to an approval of a device or its labeling. It was merely an attempt by the legislature to provide a level playing field for

newer manufacturers or manufacturers with substantially equivalent devices (in design characteristics and application) to those devices that had been in distribution and use prior to the adoption of the Medical Device Amendments.

9. The limited labeling review that does occur with a 510(k) substantial equivalence determination is reviewed only for the intended use that the device is submitted for pursuant to the 510(k). The FDA makes absolutely no determination of the safety and effectiveness of the device or the sufficiency of the labeling for any "off label" use(s).

10. Funding is extremely limited at the FDA, and the agency and its representatives are forced to make decisions regarding compliance and enforcement which take funding considerations into account.

11. Oftentimes, the agency will choose not to prosecute or vigorously pursue manufacturers despite evidence, as with the pedicle screw manufactures, that they are illegally promoting and marketing a device for off label use. Simply because the agency becomes aware that a device is being marketed and promoted for an off-label use, and doesn't act to ban the sale of the device or recall the device, in no way reflects the FDA's approval of the off-label use of that device nor the manufacturers' illegal promotional and marketing tactics.

12. Such action or inaction by the FDA is no more than a recognition of the realities of limited funding and an inability to fully police a rapidly expanding market.

13. Although sometime in 1987 the FDA was made aware of the fact that there were manufacturers who were marketing and promoting pedicle screw devices for off label use, the FDA was not aware of the widespread abuses and the extent of promotional and marketing activities which have become apparent to me from reviewing documents produced by AcroMed in this litigation.

14. The FDA was also unaware of the full extent of device failure complications and injuries caused by pedicle screw devices,

due to the manufacturers' failure to comply with the reporting requirements of the Medical Device Amendments and the Medical Device Reporting Act. It is my opinion that there was a further attempt to conceal the extent of the problem from the FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27 day of May, 1985.

/s/_____
Carl A. Larson, Ph.D., P.E.

[Remaining numbered exhibits omitted]

APPENDIX OF DEPOSITIONS

DEPOSITION OF SETH A. GREENWALD

* * * [68] Q. Did all of the patents that pertain to this pedicle screw and plate project that you
[69] worked on with Dr. Steffee pertain to spinal fixation?
A. Again, Mr. Eaton, I'd have to review the patents.

The intended application, when we first began developing the pedicle screw and spine plate at Cleveland Research Institute, was intended to be used as a spinal fixation device.

I do not recall if the actual patent application indicated a specific spinal application, although I believe the subsequent one did that emerged. There have been several, actually.

I'd have to review – I mean, it's not fresh in my mind at the moment.

Q. Okay. The work you did with Dr. Steffee with respect to his pedicle screw and plate system, in the time you worked on that project, was there any effort given or investigation done with respect to an intended use involving long bone or flat bone fixation?
A. That was not why we undertook the project.

There are a number of devices
[70] readily available for fracture or fixation of long bones.

This had a specific intended application at the time of our undertaking, and it was to be used for spinal fixation.

Q. Does that mean you did no work with respect to design or development of this system for long bones or flat bones?

A. That is correct. * * * *

[Other Depositions omitted]

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Plaintiffs' Memorandum in Opposition
to Defendant AcroMed Corp.'s Motion
to Reaffirm PTO 12 in Light of
Medtronic, Inc. v. Lohr

Filed December 2, 1996

[Text of Memorandum and Exhibits 1 and 2 omitted]

EXHIBIT 3
[Deposition Testimony of Arthur D. Steffee, M.D., 5-2-96]

[59] [Q:] The purpose of pedicle screws is to temporarily stabilize the spine to assist in fusion; is that right?

[60] A. Correct.

Q. And there are other ways to stabilize — to try to stabilize the spine without using pedicle screws, right?

A. You can use a cast. You can use older methods, Harrington Rods and things like that, but I don't use them.

Q. Why don't you use those?

A. Because the screws are better. * * *

[Exhibits 4-7 omitted]

EXHIBIT 8
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE : MDL DOCKET NO. 1014

SCREW PRODUCTS :
LIABILITY LITIGATION :

DECLARATION OF CARL LARSON, PH.D., P.E.

I, Carl Larson, Ph.D., P.E., declare:

1. I served as Director for the Division of Surgical and Rehabilitation Devices (DSRD) of the United States Food and Drug Administration from October of 1979 through January of 1992. Beginning in January of 1992, I retired and have worked privately as a Medical Device Regulatory Consultant. * * *

3. During my twelve years with the Food and Drug Administration, I was intimately involved in the management of the regulatory process pertaining to the pedicle screw manufacturers of internal spinal fixation devices utilizing pedicle screws ("pedicle screw devices"), specifically including Acromed Corp. ("Acromed"), Sofamor, S.N.C. ("Sofamor"), Danek Medical Company, and many others and I was responsible for many of the ultimate regulatory decisions made by the FDA concerning pedicle screw products.

4. I am making this declaration in support of class certification because, as I will explain in greater detail, these corporations and the medical device industry have actively promoted pedicle screw devices in derogation of the Medical Device Amendments to the Food, Drug and Cosmetic Act, and in reckless disregard for the fact that they have never been able to demonstrate with scientifically valid data or evidence that these devices were safe or effective for spinal fusion surgery.

5. The primary purpose of the Medical Device Amendments to the Food, Drug and Comestic Act, and the principal goal of my division with the FDA, was to ensure that medical devices were demonstrated to be safe and effective for their intended use **before** they were marketed. * * *

28. All of the FDA's clearance and classification decisions are based upon the intended use of the device as represented to us by the manufacturer or device proponent. If the device is promoted for a use other than that which is represented to be its intended use and which serves as a basis for Pre-Market Approval or 510(K) clearance, then that device is considered misbranded or adulterated in violation of federal law.

29. The FDA's position on pedicle screw devices has consistently been that these devices are significant risk Class III investigational devices which require an IDE and Pre-Market Approval. There has never been sufficient safety and efficacy data provided to allow such approval.

30. As of the present date, no pedicle screw manufacturer has been able to successfully complete a clinical trial under an IDE which has led to Pre-Market Approval of any pedicle screw device. Accordingly, there are no legally marketed pedicle screw devices in this county at present, nor has there ever been any demonstrated to be reasonably safe and effective for pedicle fixation.

31. The FDA's position regarding these devices was further set forth in a letter directed towards the American Academy of Orthopedic Surgeons dated July 13, 1993, in which the FDA stated.

> In this case the Medical Device Amendments are clear in language and intent. New intended uses and new devices pose a potentially significant risk to patients and are automatically classified as Class III devices and may only be marketed (and promoted for new uses) after agency approval of a Pre-Market Application (PMA). Since 1984 FDA has repeatedly informed sponsors of such products of the classification status and the conditions under which these new devices could be clinically investigated to determine their safety and effectiveness. Beginning in 1988, FDA has further notified sponsors of screw and plate medical device products submitted through the 510 (k) process of the classification of vertebral pedicle screws, limitations imposed on labelling, promotion and marketing for

devices such as bone screws, inter-vertebral body screws, sacral screws, iliac screws, bone plates, and spinal fixation systems incorporating bone screws. These 510 (k) letters now also include notice of what would constitute adulteration or misbranding of approved devices.... In sum, there are no legally marketed bone plates, bone screws, spinal screws, pedicle screws, or device systems that incorporate bone screws commercially available in the United States, that have been cleared or approved for spinal fixation when used for attachment through the pedicle of a vertebra. PMA's have been submitted for such products but FDA has refused to accept them for filing because of patient inadequacies in the applications including insufficient follow up of patients, statistically inadequate sample sizes, lack of defined clinical justifications for patient entry. Lack of valid controls and lack of discernible end points. Pedicle screw spinal fixation device systems are currently limited to commercial distribution as part of experimental protocols in over seventeen ongoing studies under the Investigational Device Exemption (IDE) provisions of the Medical Device Amendments.

32. In 1983, Dr. Arthur Steffee patented a device known as the VSP Spinal Fixation System. This device was commercially produced by Acromed Corporation, and designed as an internal spinal fixation device involving plates to be attached to the spine by means of the insertion of bone screws into the pedicles of the vertebrae.

33. In September of 1984, Acromed submitted a 510 (k) Notification to the FDA notifying us of the intent to market the VSP Spinal Fixation System as a device which was substantially equivalent to devices already on the market. See 510 (k) Notification Letter attached as Exhibit "B".

34. In December of 1984, the FDA notified Acromed that the device could not be found substantially equivalent to any predicate device because of insufficient information, and offered to reevaluate

the 510 (k) Notification if Acromed would submit additional data pertaining to safety and efficacy for its intended use. See letter from the FDA attached hereto as Exhibit "C".

35. Acromed submitted some additional information in September of 1985, which the FDA reviewed.

36. In November of 1985, the FDA notified Acromed that the device was determined to be not substantially equivalent (NSE) for its intended use. Moreover, we informed Acromed that the device was classified as a Class III significant risk investigational device, and that the device posed "potential risks (new types of safety and effectiveness concerns) not exhibited by other spinal fixation systems, such as:

(a) Greater chance of neurological deficit due to imprecise screw placement and in the event of screw failures;

(b) Pedicle fracture during placement of the screw;

(c) Soft tissue damage or inadequate fusion due to bending or fracture of device components; and

(d) Greater risk of pseudarthrosis due to instability of design."

See letter from the FDA attached hereto as Exhibit "D".

37. On December 12, 1985, a meeting was held in my office at the FDA where I was present together with Ken McDermott, Dan McGunagle and Tom Callahan from the FDA staff and Joe Radzius, Arthur Steffee, Ed Wagner and Pamela Buckman, from Acromed Corporation. The meeting was requested by Acromed to take issue with the FDA's determination that the VSP Spinal Fixation System was not substantially equivalent to any predicate device for pedicle screw fixation. At that meeting we reiterated to the Acromed representatives the four new safety and effectiveness concerns which the VSP Spinal Fixation System presented which were not present with the devices claimed to be "predicate devices" by Acromed Corporation as outlined in paragraph 36 above. We informed Acromed's representatives that premarket approval, based upon data derived from a clinical trial conducted pursuant to an appropriate

IDE was required before the VSP device could be marketed because of these new safety and efficacy concerns.

38. At this meeting, Acromed's representatives inquired as to whether the company could train surgeons in the use of the VSP device for pedicle screw fixation. In response, the FDA's representatives explicitly and specifically told Acromed's representatives that they could only train surgeons in the use of the device after an IDE was submitted and approved and could train no one other than the approved clinical investigators and only for implantation in approved clinical trials pursuant to IDE approval.

39. At no time during that meeting, or at any other meeting of which I am aware, did the FDA ever suggest that Acromed seek approval for the VSP system of plates and screws as "bone plates" and "bone screws." Acromed did raise the questions of whether it could label and sell the device as "bone plates" and "bone screws" and were told that it would have to submit separate 510 (k) applications for these purposes and that the FDA would evaluate those applications individually.

40. It was clear that if Acromed submitted separate 510 (k)'s for the use of the VSP device as a "bone plates" or "bone screws" it would have to be for the limited use defined in the FDA orthopedic devices classification category 21 CFR 888.3030, for fixation and fusion of long bones and flat bones only.

41. In December of 1985, Acromed submitted a new 510 (k) Notification for a device named the "Acromed Nested Bone Plate", and separate 510 (k) notification for a device known as a "Cancellous Bone Screw". Upon review of the technological characteristics (design and materials) for these devices, it was clear that they were identical in all technological characteristics to the components of the VSP Spinal Fixation System. In fact, one of my staff reviewers, Ken McDermott, noted this similarity in an internal memorandum which is attached hereto as Exhibit "E". Mr. McDermott requested further information from Acromed concerning the intended use of these devices.

42. In January of 1986, in direct response to questioning from the FDA, Acromed wrote and represented that these bone plates and bone screws were intended for use "in appropriate fractures of long bones of both the upper and lower extremity...", which is in complete agreement with the classification under 21 C.F.R. 888.3030.

See letter from Acromed representatives attached hereto as Exhibit "F".

43. After considering Acromed's 510 (k) applications for the "Nested Bone Plate" and "Cancellous Bone Screw", and in direct reliance upon Acromed's representation that these devices were intended for use solely in fractures of long bones in both the upper and lower extremities, the FDA issued a finding of substantial equivalence for these devices, and they were designated as Class II devices for that specific use pursuant to 21 C.F.R. 888.3030. As such, they were permitted to be commercially distributed for use in the long bones of the arms and legs. This finding can in no way be construed as permitting use of the Acromed bone screws and bone plates in the pedicles of the spine for spinal fusion procedures. Inherent in the FDA's decision and in the classification of the device, was the limitation imposed upon us at the FDA by Acromed representing in writing that the device was intended for use solely in healing fractures of the long bones. Obviously, the potential for serious injury to a patient is far greater when this device is inserted in the pedicles of the spine, millimeters away from the central nervous system and nerve roots, than the potential for injury when the device is inserted into a tibia or femur. Thus, with the risk factor being so reduced, and the fact that orthopedic surgeons have long used screws and plates in fusions of long bones, the FDA had little choice but to consider this device as substantially equivalent to devices already on the market for these intended uses.

44. There can be no question that Acromed misrepresented the intended use of the device. Indeed, I have even seen testimony from Acromed's own Corporate Designee admitting that, in fact, there

were no known clinical uses for these devices other than pedicle screw fixation in spinal fusion procedures, even though the devices were shipped to hospitals with appropriate packaging and labelling, limiting approved use of the devices to fixation of long bones. See Notes of Testimony attached hereto as Exhibit "G".

45. In addition, there is no question that Acromed actively labeled and promoted its bone plates and screws exclusively for use in spinal fixation procedures involving the insertion of screws within the human pedicles. Among other things, Acromed published a catalog describing and depicting its bone plates and screws as "transpedicular screws" and "spine plates." See Exhibit "H". Acromed encouraged spine surgeons to ignore the approved labelling and use its plates and screws in an unapproved manner in spinal fusion procedures. Acromed rewarded the surgeons by appointing them to its Medical Advisory Board, furnishing the surgeons with lucrative stock options through which they could participate in the financial growth of the company and the anticipated public offering of its stock and paying their expenses for attending meetings and symposia at which physicians were instructed in spinal instrumentation techniques using the VSP device. See Exhibit "I". Moreover, Acromed apparently prepared a booklet for spine surgeons to provide to their patients which promoted the use of VSP implants and screws in back operations. See Exhibit "J". In addition, Acromed created and disseminated to physicians a "Techniques Manual" which demonstrated the use of its plates and screws exclusively in spinal pedicle fixation procedures. See Exhibit "K". **Because the FDA never cleared or approved Acromed's bone plates and screws for any spinal applications, all of these activities by Acromed constituted misbranding and adulteration of the devices in violation of federal law**. It is my understanding that there is presently a grand jury investigation proceeding in the Southern District of Ohio investigating these charges.

46. Acromed substantially altered the design and materials of its bone plates and bone screws on at least four separate occasions

and never made additional 510 (k) applications as required by the FDA regulations each time there is a change in the design or materials of a device originally cleared by the FDA under the 510 (k) process.

47. One such example of Acromed's changing the design was the introduction of the integral nut to the screw. The December, 1985 application which Acromed submitted to the FDA for Section 510 (k) clearance to market "cancellous bone screws" related to bone screws did not have an integral nut as part of the described screw design. Bone screws with integral nuts could not be used in the repair of fractures of the long bones and could not be considered substantially equivalent to cancellous bone screws then present on the market. However, in 1986 Acromed changed the design of the cancellous bone screws to include an integral nut. Acromed never submitted an application for premarket approval with respect to this integral nut screw nor did it submit any 510 (k) notifications for this device. Since Acromed's integral nut screw was a new device which did not receive premarket approval and which was not cleared for marketing pursuant to the 510 (k) notification process, it could not be legally marketed by Acromed or used by physicians at all. Nonetheless, virtually all of the screws sold by Acromed for use with its nested bone plates were screws incorporating the integral nut design. Thus, all of the surgeries performed outside of the IDE clinical trials involving Acromed's plates and screws were performed in violation of federal law.

48. In January, 1986, Acromed applied for an investigational device exemption to study the VSP Spinal Fixation System. After submission of all of the required data, the IDE was approved and limited clinical trials were permitted to commence.

49. The sponsor/manufacturer is required as part of its IDE application to submit to the FDA the cost of the device and is not permitted to charge any more for the device than the costs of manufacture plus research and design costs. The cost of the device

must adhere to the IDE Rules which prohibit the manufacturer from making any profit on the sale of the device.

50. Prior to April of 1990, FDA inspectors gathered evidence and submitted it to the FDA Office of Compliance, General Counsel and Office of the Commissioner leading to the FDA's termination of Acromed's clinical trials and revocation of its Investigational Device Exemption for the VSP Spinal Fixation System because inspections of the investigational sites and the investigators' records revealed numerous and gross violations of the approved clinical protocol. Specifically, the FDA found that Acromed, the IRB's and its investigators were severely negligent in the monitoring and conduct of the clinical trials resulting in failure to maintain accurate data, failure to conduct adequate follow up on patients, failure to obtain appropriate informed consent from patients, and failure to report all adverse incidents related to the device. These patients were only a small percentage of those actually being implanted with the devices. Therefore, in an effort to protect the public health, in April of 1990 the FDA revoked Acromed's clinical trials for its VSP plates and pedicle screws, without granting the company an opportunity for a hearing because it was determined that the risk to the public health was so great. See letter from FDA to Acromed attached as Exhibit "L".

51. There has been absolutely no data ever submitted to date by Acromed or any other manufacturer, nor any data available through the literature or elsewhere, sufficient to satisfy the FDA's concerns regarding the four new safety and efficacy questions.

*** I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 26th day of November, 1994.

/s/
Carl Larson, Ph.D., P.E.

[Exhibit A to Declaration of Carl A. Larson, Ph.D., omitted]

Exhibit B to Declaration of Carl A. Larson, Ph.D.

Buckman Company, Inc.
921 Calle Verde
Martinez, California 94551
(415) 972-7740

September 4, 1984

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Document Control Clerk: 510K – NOTIFICATION

The attached information is submitted in accordance with Part 807, Subpart E of the code of Federal Regulations Chapter I, Title 21.

It is our opinion that the "Variable Screw Placement" (VSP) Spinal Fixation Plating System is substantially equivalent to devices manufactured and marketed prior to May 28, 1976. We conclude that the following information supports our position.

We further believe that some of the information included herein is of a confidential nature. Neither the manufacturer nor I have any knowledge of the release of this information to any party other than the recognized employees or agents of AcroMed Corporation. We agree to notify the Food and Drug Administration when a change

in this situation occurs. Until then we suggest that this document not be released through FOI requests or any other way.

As the official correspondent for AcroMed Corporation for this product line, please direct any correspondence relative to it to my attention at the address indicated for Buckman Company, Inc.

We thank you in advance for your prompt consideration of this submission and will be happy to provide additional information as you may require.

Sincerely,

/s/
Pamela M. Buckman, R.N., M.S.

PMB/ds
cc: Edward Wagner, AcroMed Corporation
Enclosure: 510K Notification (3 copies)

Exhibit C to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

[Date-stamped: December 19, 1984]

Re: K843600
Variable Screw Placement (VSP)
Spinal Plate Fixation System
Regulatory Product Class: III
Dated: September 4, 1984
Received: September 12, 1984

Ms. Pamela M. Buckman,
R.N., M.S.
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Dear Ms. Buckman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined that the information is your submission does not demonstrate that your device is substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that immobilization of the spinal column by means of an intervertebral fixation plate with specifically-designed screws in the manner that you propose to achieve spinal fusion and correct various spinal conditions (such as adult onset scoliosis and spondylolisthesis) was not in use before May 28, 1976, and that insufficient data documenting the safety and effectiveness of the VSP Spinal Plate Fixation System were submitted. We may re-evaluate this determination if you provide:

(a) data establishing that the specially-designed screws and plate fixation system are capable of withstanding dynamic simulation tests under worst-case loading conditions which are representative of the actual use, in-vivo conditions; and

(b) data and results from a clinical study including several investigators which has sufficient number of patients and duration to document the long-term safety and effectiveness of the VSP Spinal Plate Fixation System for each proposed indication of use (i.e., adult onset scoliosis and spondylolisthesis).

Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to haves approved premarket approval application (PMA) before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device exemption regulation, which must be followed if your devices are used in a clinical investigation.

Petition for Reclassification. If you believe that your devices should not have to undergo premarket approval before they are commercially distributed, you may petition FDA for reclassification of your devices under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation.

If you have additional information that may alter this decision or if you need any information concerning our decision or the alternatives available to you under the law, please contact James G. Dillon, Ph.D., at (301) 427-7238.

Sincerely yours,

/s/
Robert G. Britain
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

Exhibit D to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
8767 Georgia Avenue
Silver Spring, MD 20910

Ms. Pamela M. Buckman, R.N., M.S.
Buckman Company, Inc.
921 Calle Verde
Martinez, California 94553

Re: K853913
Variable Screw
Placement (VSP)
Spinal Plate Fixation
System
Dated: September 20, 1985
Received: September 23, 1985

Dear Ms. Buckman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device is not substantially equivalent to devices marketed in interstate commerce

prior to May 28, 1976, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that there has not been adequate demonstration that there was a pre-amendment device labeled, advertised, or otherwise promoted, with a design substantially equivalent to the VSP Spine Plate System and on the fact that it poses potential risks not exhibited by other spinal fixation systems, such as:

1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;
2. pedicle fracture during placement of screw;
3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and
4. greater risk of pseudoarthrosis due to instability of design.

Therefore, your device is classified by statute in class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires class III devices to have an approved premarket approval application before they can be legally marketed unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application (PMA), statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a class III device may be distributed only for investigational use. Enclosed is a copy of the investigational device

exemption regulation, which must be followed if your device is used in a clinical investigation.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into class I or II, would be a violation of the Act. Clinical investigations of your device must be in accordance with the investigational device exemption regulation;

If you need any information concerning our decision or the alternatives available to you under the law, please contact Thomas J. Callahan, Ph.D., at (301) 427-7156.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Exhibit E to Declaration of Carl A. Larson, Ph.D.

Department of Health & Human Services
Public Health Service

MEMORANDUM

Date:

From: Reviewer(s) – Name(s) Ken McDermott

Subject: 510(k) NOTIFICATION – K855224

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed device.s

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__x__ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

[Handwritten: This same implant was submitted in K853913 for spinal fixation and was NSE. The firm resubmitted the device here, without the screws and nuts which were included in K853913, for use as a common bone plate. I requested a list of indications from Mr. Schlerf 1/10/86.]

The submitter requests: Class Code w/Panel:

_____ No Confidentiality _____

_____ Confidentiality for 90 days

__X__ Continued Confidentiality exceeding 90 days

REVIEW:

(BRANCH CHIEF) (DATE)

FINAL REVIEW:

(DIVISION DIRECTOR) (DATE)

[Exhibit F to Declaration of Carl A. Larson, Ph.D. omitted]

Exhibit G to Declaration of Carl A. Larson, Ph.D.

DEPOSITION TESTIMONY OF GEOFFREY J. PORTER
Robert Baker v. Donald L. Myers, et al., March Term 1990
No. 4915 (Ct. Com. Pls. Phila. Cty.)

[17] * * * Q. So, am I correct based on your earlier testimony that the only place through where these plates are actually designed for use is the spine?

A. That is correct. * * *

Exhibit H to Declaration of Carl A. Larson, Ph.D.

[See following inserted pages, which are redacted portions of exhibit]

No. 6861

AcroMed® PRICE LIST

Effective June 1, 1986

BEST AVAILABLE COPY

Supersedes all previous price lists.
Please dispose of all previous price lists.

VSP SPINE PLATES

Order No.	Description	Unit Quantity	Price
2025-01*	VSP Spine Plate - 1 Slot	2	625.00
2025-01.5*	VSP Spine Plate - 1.5 Slot	2	650.00
2025-02*	VSP Spine Plate - 2 Slot	2	675.00
2025-02.5*	VSP Spine Plate - 2.5 Slot	2	700.00
2025-03*	VSP Spine Plate - 3 Slot	2	725.00
2025-03.5*	VSP Spine Plate - 3.5 Slot	2	750.00
2025-04*	VSP Spine Plate - 4 Slot	2	800.00
2025-04.5	VSP Spine Plate - 4.5 Slot	2	850.00
2025-05	VSP Spine Plate - 5 Slot	2	900.00

VSP BUTTRESS CLAMPS

2025-10*	VSP Sacral/Buttress Clamp - 30° Under	2	90.00
2025-11*	VSP Sacral/Buttress Clamp - 45° Under	2	90.00
2025-12*	VSP Sacral/Buttress Clamp - 30° Over	2	90.00
2025-13*	VSP Sacral/Buttress Clamp - 45° Over	2	90.00

PLATE SPACER WEDGE

2025-15*	Plate Spacer Wedge	1	6.00

*Recommended for intial order
U.S. and foreign patents pending

VSP TRANSPEDICULAR AND SACRAL SCREWS

Order No.	Description	Unit Quantity	Price
2026-20*	VSP Sacral Screw	2	150.00
2026-22	VSP Transpedicular Screw	2	150.00
2026-24*	VSP Transpedicular Screw	10	750.00
2026-28	VSP Transpedicular Screw	10	750.00
2026-32*	VSP Transpedicular Screw	10	750.00
2026-34	VSP Transpedicular Screw	1	85.00

SCREW NUTS

2026-1000	3/8 in. Screw Nut	1	3.00
2026-1100	5/16 in. Lock Nut	1	2.00

*Recommended for intial order
U.S. and foreign patents pending

VSP SPINAL SURGERY INSTRUMENTS

Order No.	Description	Unit Quantity	Price
2025-4000	Basic VSP Instrument Set (See below)		1,094.00
2025-40	Screw Wrench with Hex Socket, T-Handle	1	50.00
2025-41	Tapered Nut Wrench, T-Handle with Hex Socket	1	65.00
2025-4100	3/8 in. Open End Nut Wrench	1	45.00
2025-4101	3/8 in. Nut Driver with Jacobs Shank	1	55.00
2025-42	Lock Nut Wrench, T-Handle	1	65.00
2025-4201	Lock Nut Driver with Jacobs Shank	1	55.00
2025-70	VSP Bone Tap - for 5.5mm Screw	1	95.00
2025-72	VSP Bone Tap - for 6.25mm Screw	1	95.00
2025-74	VSP Bone Tap - for 7.0mm Screw	1	95.00
2025-45	Screw Alignment Bar	1	75.00
2025-46	Screw Alignment Rods set of 2		40.00
2025-47	VSP Pedicle Probe	1	95.00
2025-48	VSP Plate Contouring Templates Set of 4		25.00
2025-49	VSP Pedicle "Sounder"	1	140.00
2025-50	VSP Intervertebral Spacer Wedges, Set of 3		370.00
2025-51	VSP Impactors Set with Quick Release Handle and Case		1,490.00
2025-52	Spinal Elevators ("Persuaders") Set of 2		225.00
2025-53	Foraminal Probes Set of 6		490.00
2025-54	Pedicle Locator		9.00

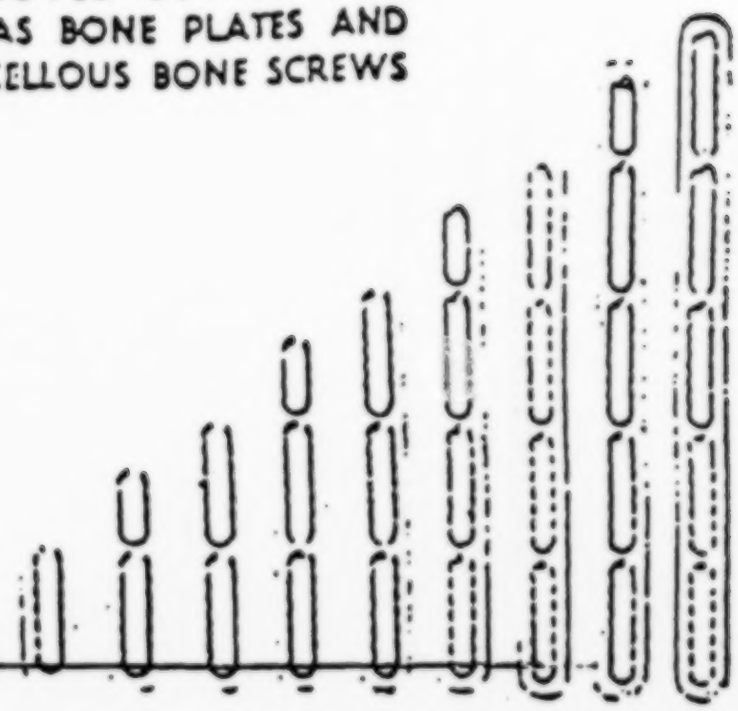
Recommended Basic VSP Instrument Set consists of: 2025-40, -41, -4100, -42, -70, -72, -74, -45, -46, -47, -49, -52 and -54

FOR INVESTIGATIONAL USE

VSP SPINE PLATES

Segmental spine plate system for internal fixation of the unstable lower thoracic and lumbar-sacral adult spine at single and multiple segmental levels. Transpedicular Screws (2026-22 through -34) placed bilaterally through the pedicles and into the vertebral bodies and stabilized with VSP Spine Plates secured by specially designed Nuts provide immediate, strong and rigid fixation. Available in 1 through 5 slots in half slot increments. Longer plates available on special orders.

APPROVED BY FDA FOR USE AS BONE PLATES AND CANCELLOUS BONE SCREWS



01° 1.5° 2° 2.5° 3° 3.5° 4° 4.5 5.

Order No.	Description † Length	Width
2025-01	1.75 in. (44mm)	.62 in. (16mm)
2025-1.5	2.70 in. (68mm)	.62 in. (16mm)
2025-02	3.25 in. (84mm)	.62 in. (16mm)
2025-2.5	4.20 in. (106mm)	.62 in. (16mm)
2025-03	4.75 in. (120mm)	.62 in. (16mm)
2025-3.5	5.70 in. (144mm)	.62 in. (16mm)
2025-04	6.25 in. (158mm)	.62 in. (16mm)
2025-4.5	7.20 in. (182mm)	.62 in. (16mm)
2025-05	7.75 in. (196mm)	.62 in. (16mm)

U.S. and foreign patents pending
* Recommended for initial order
† VSP Plates are manufactured of certified implant grade Stainless Steel

[Exhibit I to Declaration of Carl A. Larson, Ph.D. omitted]

Exhibit J to Declaration of Carl A. Larson, Ph.D.
[See following inserted pages]

[Remaining Exhibits to Declaration of Carl A. Larson, Ph.D., omitted]

Spine Plat
Patier
Informatio

Sanford H. Davne, M.D.
Donald I. Myers, M.D.

1015 Chestnut Street
Mezzanine
Jefferson Building
Philadelphia, PA 19107

BEST AVAILABLE COPY

Low back pain, with or without accompanying leg pain, is the result of a number of causes, either separately, or in combination.

1. Your pain may be due to the pressure of soft tissue, such as ligaments or bone on a spinal nerve. This pressure irritates the nerves that, in turn, causes back and/or leg pain.

2. Another major cause of pain occurs when one vertebra rubs against another vertebra when you move your back. The pain that is produced in this way may decrease or go away entirely if you immobilize your spine. Unfortunately, the only way that you can do this, without surgery, is to stay in bed, flat on your back. In that respect, bed rest is a solution, but who wants to live the rest of their life flat on their back?

3. Previous unsuccessful spine surgery can also be a cause of continuing back and leg pain.

4. Accidents, either at home or on the job, that cause trauma to your back, such as fractures, can cause back and leg pain.

5. Tumors, originating in the spine, or from elsewhere in your body, can cause pressure in your spine and result in back and leg pain.

6. All sorts of misalignments of your spine, either vertically, or from side-to-side, can give you pain in your back or legs.

All of these causes of pain are either directly or indirectly related to the relative stability and proper alignment of your spine.

Your doctor, after a careful and thorough physical examination that includes reviewing the results of sophisticated tests and x-ray procedures will be able to diagnose your condition and recommend a course of treatment that should relieve your symptoms.

TREATING LOW BACK PAIN

In order to correct your spinal instability and/or alignment problems, your surgeon has chosen an operation that includes fusion of your vertebra, nerve root decompression, and fixation using spine plates.

Spinal fusion is designed to stop all motion between any two vertebra in your back. This is done by inserting blocks of bone (either your own bone, taken from your hip, or bone obtained from a bone bank) into the space between the vertebra. These bone blocks, or grafts, eventually grow together, or fuse, and in doing so entirely eliminate the movement of this section of the spine and remove one of the initial causes of back and leg pain. (Fig. 3)

You can reasonably expect these bones to fuse into a solid mass in about six months.

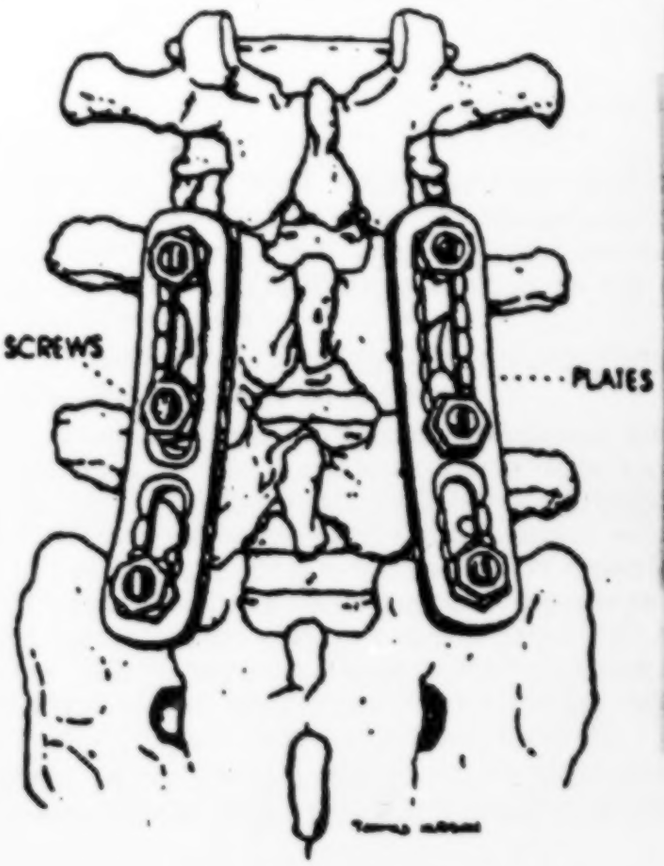


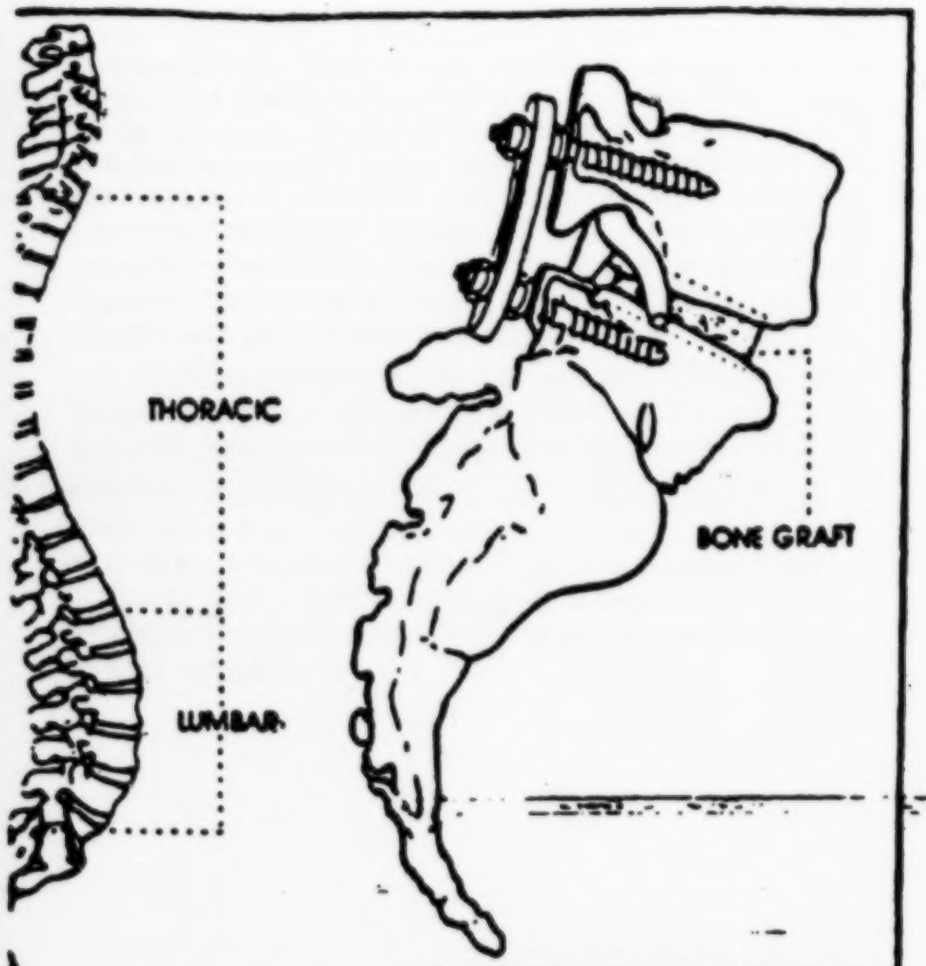
Fig. 1 Spine plates and screws in place

A nerve root decompression is achieved when your surgeon removes some or all of the bony structure and soft tissue that covers the top of your spinal column, thereby freeing or "decompressing" the nerve roots that branch out from your spinal cord. When this pressure is gone, another cause of back and leg pain is alleviated.

Finally, in order to insure that all this work will give you lasting relief from back and leg pain, your surgeon completes the operation by using spine plates to stabilize your back in the best possible position. Achieving spinal fusion in an unstable or misaligned spine without spine plates is very difficult because there is nothing to prevent your spine from moving while the bone between your vertebra is fusing.

Studies have shown that fusion progresses best when the spine is rigid and the bone grafts are kept compressed under constant pressure. In order to decrease motion in your spine and in order to add rigidity to your spine after extensive nerve root decompression, spine plate surgery was developed.

Spine plates consist of two stainless steel plates with nested slots for the insertion of screws. (Fig. 1) At the right time during your surgery, screws and spine plates are inserted and joined together on each side of the vertebral spine, and adjusted to bring the vertebra into firm alignment. Once this has been achieved, all of the elements that your surgeon has brought together work to give your spine a better shape, and prevent movement of the vertebra, thereby eliminating another cause of pain.



2 Spinal column

Fig. 3 Plates and screws attached above and below

Your surgeon has determined that your particular problem originates in the spinal column at one or more vertebral levels in the thoracic or lumbar spine (Fig. 2) and will be able to indicate the probable problem area to you on a model or drawing. It is important for you to understand that a back problem may exist at one or more of these levels. When spine plates are used in conjunction with a spinal fusion and nerve root decompression, the plates are usually applied to one vertebral level above and to one vertebral level below the affected area, in order to insure adequate fixation while the vertebra are fusing. (Fig. 3)

As is the case with surgery of this magnitude, a moderate amount of blood is lost during this procedure. To replenish this loss, blood transfusions are commonly administered during surgery. Typically, this operation will take from 2 to 4 hours, depending on the number of levels involved, and the extent to which the spine needs to be realigned or repaired.

POST-OPERATIVE EXPECTATIONS

Length of Hospitalization: On the average, 10 or 14 days. However, since your recovery rate will vary according to such factors as age, weight, fitness level and general health, the actual length of your hospital stay will be determined in consultation with your surgeon. You will probably be up and walking 1 to 3 days following your surgery.

You will experience some fatigue and post-operative pain, but as you regain your strength, and begin caring for yourself the fatigue and pain will diminish and eventually disappear as you gradually resume your normal pre-operative activity level.

All forms of lifting and carrying are to be avoided until otherwise indicated by your surgeon.

You may wonder if you will be able to bend over following spine plate surgery. The answer is, "Yes!" Functionally, spine plates do not hinder your motion. You will probably regain full or almost full range of motion.

POSSIBLE COMPLICATIONS

Any surgery, no matter how minor or major, carries with it possible complications. The following list of complications is included for you to discuss with your surgeon so that you will be able to make the best decision possible in your case. If you have any other concerns, please feel free to speak frankly with your doctor before agreeing to undergo surgery. Sharing your concerns, and resolving reasonable doubts that you have will contribute to your peace of mind, and will ultimately allow you to chart the best course of action.

1. **Infection.** This is a serious complication. To decrease the likelihood of infection, antibiotics are administered as a preventive measure. If you are allergic to specific antibiotics, remember to tell your doctor before surgery. There are many alternatives available. In the event that an infection does occur, prompt treatment will resolve the problem quickly and with a minimum of discomfort and risk. Sound post-operative care and observation by hospital staff will minimize the chance that an infection will develop. Follow your doctor's directions faithfully and infection should not be a problem.

2. **Screw Breakage.** If a screw becomes loose or breaks, it may need to be surgically replaced and/or removed. Your implants are not intended to replace normal body structures, or bear the weight of the body in the presence of incomplete bone healing or fusion. A delayed fusion or non-union of bone, which may occur for reasons beyond the control of the surgeon, will result in excessive and repeated stresses that are transmitted by the body to the screw.

Due to normal metal fatigue, excessive and repeated stress can cause eventual bending and/or breakage of screws. A bent or broken screw, however, does not necessarily determine the success or failure of the procedure. As the bone heals, the plates and screws are no longer functional, although they remain in place permanently.

3. **Bursitis.** Sometimes a small protective pocket of tissue, or bursa, develops over an irritated or surgically altered

area. The swelling that occurs may cause tenderness, and the bursa may need to be evaluated. In some cases the screw that seems to be causing the tenderness may have to be removed. In other cases, the swelling subsides and the problem goes away. In either case, consultation with your doctor is indicated, and an appropriate course of treatment should be decided upon. In many cases, conservative treatment, that is, taking a wait-and-see approach, is the best choice. In all cases, you need to work closely with your physician to decide what is best for you.

4. Continued Pain. Usually, pain associated with surgery recedes with time. On rare occasions, you may find that the pain continues. If this happens to you over an extended period, inform your doctor of your lack of progress, and work together to determine if further evaluation is indicated.

5. Dural Leak. The outer membrane covering the spinal cord is called the DURA MATER. Sometimes during surgery, or more infrequently, during pre-operative studies, this membrane is punctured. If this happens, spinal fluid leaks or seeps into the surrounding tissues. This leakage is readily detected by your physician, and if the puncture does not heal, further surgery is sometimes needed to repair the leak. Your surgeon will be able to discuss the indications for this complication with you and describe what is done in this situation.

6. Non-Union. This complication results when the bone fails to fuse, or join. During the operation your surgeon inserts a bone graft to stabilize your spine. Usually, the graft fuses and becomes solid. Sometimes, however, for reasons that are not fully understood, the bone graft does not fuse. This non-fusion or non-union may subsequently cause some discomfort. Non-fusion can be detected in post-operative x-rays, and may be the cause of some discomfort. If subsequent x-rays fail to show progress toward fusion and your discomfort continues, the first grafts may have to be removed and replaced with new grafts. As noted above, a non-union may also result in screw breakage. Replacing the bone graft usually resolves this complication. Again, your surgeon is best equipped to discuss this complication with you, and to chart an appropriate course of action.

CONCLUSION

Although each patient is unique, you should notice a marked improvement in your condition after spine plate surgery. Most patients achieve results, and are eventually free of pain and better able to participate in all or most of their desired normal daily activities. Now that you have had a chance to read and think about spine plate surgery, you should take the time to carefully weigh the pros and cons presented in this pamphlet and discuss your situation with your surgeon.

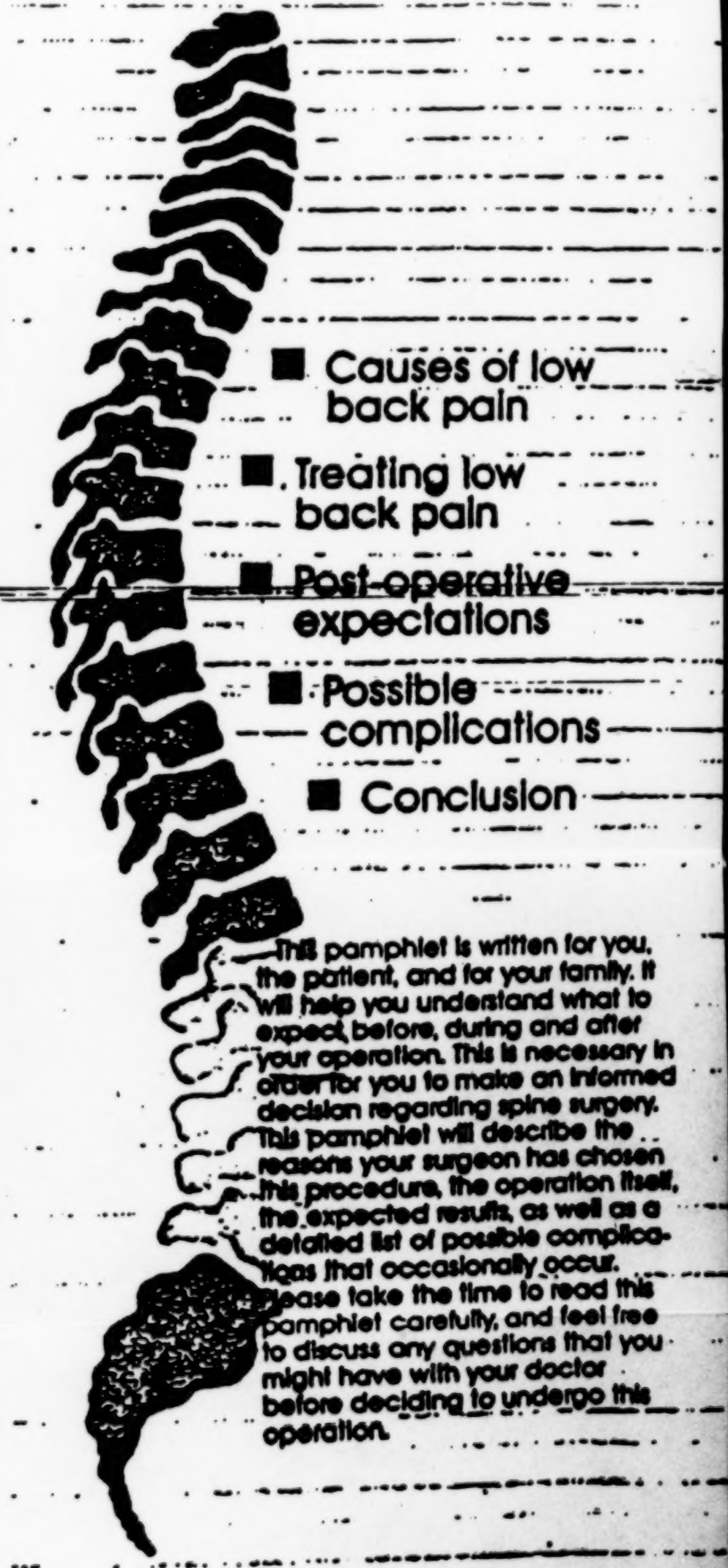


EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 1014

THE DEPOSITION OF PAMELA BUCKMAN
MARCH 20, 1996

*** [154] *** Q. It was the FDA's position that your submission did not demonstrate that any manufacturer had produced and labeled a product for pedicle placement that would qualify as a predicate device?

A. That's right.

Q. You say that, "FDA made it to clear to

[160] us that the VSP system must be handled through the IDE/PMAA mechanism for spine indications." That was consistent with your recollection of that meeting?

A. That's right.

Q. Who specifically at the FDA made that clear?

A. It would have been Dan or Tom, Dan McGunagle or Tom Callahan.

Q. You say, "They also made it clear that they would consider the VSP plate and the VSP screw as a bone plate and cancellous bone screw respectively. Dan McGunagle made a comment to the effect that we would be required to satisfy the requirements for a 510(k) for each product but that they promised to review these documents promptly."

Whose idea was it to consider the VSP plate and VSP screw as a bone plate and bone screw?

A. Dan McGunagle's.

Q. Had anyone from AcroMed brought up that suggestion in the meeting?

A. No.
[156] Q. At what point in the meeting did that suggestion come up?
A. I don't remember.
Q. Do you remember — as specifically as you can, can you tell me what was said about that?
A. Dan suggested that the plate and the screw would be reviewed as a bone plate and a bone screw if in fact we could produce a document that allowed them to find a substantially equivalent rendering or decision based on what we submitted.
Q. In that meeting, to your recollection, did anyone tell anybody at the FDA that the VSP plate or the VSP screw had clinical applications other than in the spine?
A. Dr. Steffee.
Q. And specifically what did Dr. Steffee tell the FDA about the plate and screw?
A. I specifically asked Dr. Steffee toward the conclusion of the meeting if that bone plate and bone screw could be used anywhere other than the spine, and he clearly said, "Yes, I've done it."
* * * [160] * * * Q. Was there any discussion about safety and effectiveness concerns with the VSP plate and screw if it was to be sold as a bone plate and bone screw?
A. No.
Q. To your understanding, did the FDA as of this meeting — as of the conclusion of this meeting in December of 1985 still pose those same safety and effectiveness concerns that we discussed earlier relating to this device?
A. For its use in the spine?
Q. Yes.
A. Yes. * * *
[420] * * * Q. Ms. Buckman, as early as 1985, am I correct that the FDA had communicated to you in words or substance that they had concerns about the safety and effectiveness of pedicle screws?
A. Yes.

Q. Those same concerns you communicated to AcroMed. Is that correct?
A. Yes. * * * *

EXHIBIT 10

December 21, 1985

Edward Wagner
AeroMed Corporation
2450 Prospect Avenue
Cleveland, OH. 44115

Dear Ed,

So that we may understand where we are and where we are going, I thought it wise to commit a few issues to writing.

Report of Meeting with FDA December 12, 1985, Present for FDA were Ed March, Tom Callahan, Dan McGungle and Ken McDermott. Present for AcroMed were yourself, Dr. Steffe, Dr. Graves, Mr. Radzius and myself.

After some discussion, it was apparent that FDA will not accept the 510K as means for reviewing the clinical data for the VSP plate in the "spine" location. On the other hand, they readily agreed that bone plates and bone screws — labeled as such — are "510K able".

Labeling which specifies or implies use of the plate or screws in the spine can only be reviewed via the PMAA process. Dan McGunagle told as we could go to a PMAA on the data we have with the 153 patients. An IDE is only necessary if we wish to add to the number of patients in the study group. The orthopaedic panel typically relies on 100 or more patients with a minimum two year follow up period.

To increase our chances of approval of the PMAA we will need to update the data on the original 153 patients to capture the longer follow up. Additionally, I feel we should gather data from one more

center. Dr. Steffee suggested Seattle. In my experience, three centers is usually the minimum the panel likes to see.

We discussed the pros and cons of filing an IDE for the spine indications. I think we all agree that the patients studied thus far have all been Dr. Steffee's patients and/or under his very close supervision and direction. If you wish to add investigators and display the device at AAOS, we must have an IDE.

Timing is obviously very important here as the AAOS opens February 20, 1986. This is how I suggest we proceed.

1. File a 510K for the bone plate immediately.
2. File a 510K for the bone screws imediately.
3. File an IDE for spine indications for the plate/screw system. This should be accomplished as early in January 86 as possible.

We probably won't get approval on all this by AAOS time. However, we will be on the right track and I believe FDA will work with us to develop appropriate language etc. for use at the AAOS.

Please look at the instruments that you want to show. Are there any that we have not filed on a 510K?

Please have Dr. Steffee send us the information we discussed right away. This includes articles on screws without hex heads, the IRB approval letter from St. Vincents, the informed consent form you have used in the past, the name and address of the surgeon in Seattle and anything else you can think of!

In the meantime you should review the labeling on the bone plates and screws. There should be no language which suggests the indications for use of the plates and screws other than in "bone". Which bone is up to the surgeon to decide.

We will continue to work on the package inserts for you. Our first priority will be something to go into the IDE as proposed labeling for the spinal indications.

Also for the IDE, we will design a data collection form for use with our established data management and analysis programs. Much of this has been initiated already for the data collected to date. Dr. Steffee indicated that Lynn Topham is working on some kind of program along these lines. Please remind Dr. Steffee to have Lynn call us. We will begin discussions here with Dr. Carlov our computer specialist.

In regard to your letter to Mr. Eckart, it is thorough and well written. The arguments you make have been stated before and continue to be areas of concern. I personally question whether or not anything is to be gained by sending the letter. On the other hand, I'm not sure anything will be lost either. The only risk I see is the possibility of offending a reviewer at FDA or a panel member. Frankly, I don't think this is very likely. Certainly the decision is up to you. Perhaps Joe Radzius would have more to say on this topic.

Speaking of Joe, he mentioned that he would draft a letter to attempt withdrawal of all information previously submitted on the VSP under a 510K. For competitive reasons, I think this would be wise. Perhaps you should remind him. If he does not have the time, I can write this letter for you. Please let me know what you and Joe decide.

Well, this should keep us busy for a day or so at least! It was good to see you. I look forward to meeting with you and Dr. Steffee in New Orleans. By the way, I have rooms blocked at the International Hotel. Do you need any? See you soon.

Sincerely,

/s/

Pamela M. Buckman

cc: Joseph Radzius, Esq.

[Exhibits 11-41 omitted]

EXHIBIT 42

Department of Health & Human Services
Public Health Service
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Oct. 7, 1991

Mr. William Christianson
Regulatory Affairs
AcroMed Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

[Received: Oct. 10, 1991, AcroMed Corporation, Cleveland, Ohio]

Dear Mr. Christianson:

We have received your letter of July 5, 1991, and the two-page package insert entitled, "VSP Bone Plates and Bone Screws," which was provided for our information. The comments set out below reflect positions that undoubtedly have been known to your company for years.

The information we have indicates that AcroMed has promoted, advertised, represented, and commercially distributed VSP Bone Plates and Bone Screws for use in the spine, and that this was the intended use for these devices from the start. As you know, VSP

Bone Plates and Bone Screws are Class III medical devices when intended for use in the spine, and, therefore, should have had an approved premarket approval application (PMA) for this use. Since AcroMed has never had such approval, it has never had any legal right to label (or advertise, promote, represent, or commercially distribute) VSP Bone Plates and Bone Screws for use in the spine. AcroMed received FDA approval of an Investigational Device Exemption (IDE) application (G860013), which permitted limited distribution of the VSP Bone Plate and Bone Screw for use in the spine as part of a controlled clinical investigation, subject to the requirements of 21 CFR Part 812; however, this IDE was withdrawn in our letter dated April 26, 1990.

To date, FDA has not approved AcroMed's PMA application for the Variable Screw Placement (VSP) Spinal Fixation System (P900040). As you know, without such approval, AcroMed cannot lawfully label, advertise, promote represent, or commercially distribute VSP Bone Plates and Bone Screws for use in the spine. Any direct or indirect references to the use of VSP Bone Plates and Bone Screws for spinal fixation, including any references to investigational use, or any distribution of these devices for this intended use, except in accordance with 21 CFR Part 812, is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Moreover, any representation that these devices are approved for investigational use in the spine under 21 CFR Part 812 is also false and misleading in light of FDA's withdrawal of AcroMed's IDE. Unless and until AcroMed obtains from the FDA an approved PMA for the VSP Spinal Fixation System (P900040), labeling revisions will not prevent the VSP Bone Plate and Bone Screw from being adulterated and misbranded medical devices.

Sincerely yours,

/s/

William H. Damaska
Director
Division of Compliance Operations
Center for Devices and Radiological Health

cc:
Dr. Arthur D. Steffee
9994 Music Street
Novelty, Ohio

Jeffrey N. Gibbs, Esq.
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20005

[Exhibit 43 omitted]

EXHIBIT 44
MEMO OF MEETING

BETWEEN: Jeff Gibbs, Jim Phelps — Hyman, Phelps and McNamara

Mr. Christianson, Ms. Lanlatz — Acromed Corporation

AND

Ron Johnson-CDRH, Dr. Nirmal Mishra-CDRH, Karen Stutzman-CDRH, Edie Snyder-MIN-DO, Larry Spears-CDRH, Charles W. Sedgwick-CIN-DO, Mr. Steve Keller-DOJ

DATE: March 7, 1994

In a meeting arranged by the Director of Compliance for CDRH, Ron Johnson, Messrs. Jeff Gibson and Jim Phelps of the law firm Hyman, Phelps, and McNamara, and Mr. Christianson and Ms. Lanlatz of the Acromed Corporation met to discuss the Corporation and their potential prosecution.

The subject of the meeting generally followed the format of the attached 12-1-93 letter to the Center. The counsel for the firm, Mr. Gibbs, emphasized the need to have the industry and the FDA cooperate and that prosecution would be an impediment to this cooperation. Specifically, the cooperative efforts involved an industry-funded study (17 firms) which was reviewing the pedical screw issue. Mr. Christianson advised that because of the time interval involved in the study (1990 and 1991), most data collected would come from Acromed. The counsel advised that an indictment of Acromed would cause firms to be less willing to cooperate with the study.

A second issue for Acromed is the industry's (Acromed) view that the Center is sending mixed signals to the industry by "approving systems" for non-pedical use when the known use (supposedly to the center) is for the pedical.

A third area visited was the issue of responsibility. Mr. Christianson advised that the corporate management had changed, i.e. Mr. Ed Wagner was retired (or resigned?) and that the Board of Directors had been expanded to include two "outside" members. Ms. Lanlutz acknowledged that both William and Arthur Steffee were still board members.

The fourth issue concerned "confusion in guidance" on how products should be labelled, i.e: requiring the statement on pedical screws etc., (i.e. "not for pedical use" and then requiring the removal of the same).

Emphasis was placed upon FDA being unable to "keep up with technology" and suggesting that the FDA's failure to approve the VSP system and pedical screw was no reason for an innovative and competent firm to not market the state of the art technology.

Acromed's counsel highlighted that any legal action on the government's part would foster additional private suits. We were advised that there were currently 6 or 7 class action lawsuits pending against Acromed. The current "20/20" program acknowledging a grand jury investigation has had an adverse effect on the firm. Mr. Christianson advised that the firm has paid an estimated $700,000.00 to date responding to subpoenas, etc.

The firm's letter and presentation was a plea to drop any further grand jury/prosecution action based upon the mixed signals received by the firm and the unfairness implied by the prosecution proposal. The representative asserted several times that other firms were marketing not only pedical systems but other medical devices for purposes for which they were not approved [i.e. 510 (k)] and that although FDA was aware of such practices, only Acromed was the subject of a potential prosecution. The firm's counsel advised that after two years, the firm had not as yet received a copy of "the 85 document" on the meeting the firm had with members of the CDER staff.

cc: Brunswick R.P.
Leonard J. Farr
Karen Stutzman

[Remaining exhibits omitted]

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Buckman Company's Reply Memorandum
In Support Of Motion to Dismiss Omni Complaint
For Failure To State A Claim Upon Which Relief
May Be Granted

Filed January 31, 1997

[Text of Reply Memorandum omitted]

EXHIBIT 1

Jones, Day, Reavis & Pogue
North Point
901 Lakeside Avenue
Cleveland, OH 44114

* * * March 1, 1996

Edward J. Parr, Jr., Esq.
Office of General Counsel
United States Food and Drug Administration
Department of Health and Human Services
Rockville, Maryland 20857

Re: Orthopedic Bone Screw Litigation

Dear Mr. Parr:

The Food and Drug Administration is familiar with the pending litigation involving orthopedic bone screws. You and other counsel

for the FDA have attended depositions in these cases, and the FDA has obtained the right to review the discovery record generated in the federal MDL proceeding. The FDA is therefore now presumably aware that plaintiffs have alleged that AcroMed Corporation defrauded the FDA during a meeting between AcroMed and FDA officials that occurred on December 12, 1985. Those allegations are unfounded; indeed, they are belied by a memorandum written by an FDA official. I have enclosed a copy of that memorandum for your information.

In light of the allegations made by plaintiffs, and their potential impact on this litigation, AcroMed Corporation would like to take very limited depositions on written questions, pursuant to Federal Rule of Civil Procedure 31, of Thomas Callahan and Daniel McGunagle, two FDA employees who attended the meeting on December 12, 1985. We believe that these limited depositions are essential to allow us to demonstrate that plaintiffs' allegations of fraud on the FDA are false. The limited depositions that we contemplate will not invade any deliberative process of the FDA or unduly interfere with the conduct of the Agency's business.

Please consider this letter as a request for testimony on behalf of AcroMed Corporation pursuant to applicable FDA regulations, including 21 C.F.R. § 20.1. To assist you and the questions that we propose to use to take the depositions under Rule 31.

I look forward to hearing from you on this matter. Thank you for your assistance.

Very truly yours,

/s/
Richard I. Werder, Jr,

Enclosures
bcc: Stephen S. Phillips, Esq.

What is your name?

By whom are you employed?

For how long have you been employed by the FDA?

What is your position with the FDA?

For how long have you held that position?

What was your position at the FDA as of December 12, 1985?

Did you attend a meeting between representatives of AcroMed Corporation and FDA officials on December 12, 1985?

Who was present during that meeting on behalf of FDA?

Who was present during that meeting on behalf of AcroMed?

Describe in as much detail as you can remember the conversation that took place during the December 12, 1985 meeting.

During the December 12, 1985 meeting, did the AcroMed representatives demonstrate to the FDA the use of plates and screws in a model of the human spine?

During the December 12, 1985 meeting, did FDA officials tell AcroMed that FDA would not clear AcroMed's plates and screws for marketing if they were labeled as a "spine plate fixation system"?

During the December 12, 1985 meeting, did FDA officials tell AcroMed that because of the similarities between AcroMed's plates and screws to ordinary bone plates and screws, AcroMed's plates and screws could be cleared for marketing when labeled as simple bone plates and bone screws?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed's representatives that Dr. Arthur Steffee could publish papers in the peer-reviewed journals describing his findings

from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed's representatives that Dr, Arthur Steffee could publish papers in the scientific literature describing his findings from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did Daniel McGunagle advise AcroMed that Dr. Steffee could make scientific presentations at professional society meetings describing his findings from the use of plates and screws for spinal fixation without violating the Food, Drug and Cosmetic Act?

During the December 12, 1985 meeting, did FDA officials discuss with AcroMed FDA's policy of not regulating the practice of medicine by individual physicians?

During the December 12, 1985 meeting, did an FDA official indicate that if individual physicians chose to use plates and screws for spinal fixation, that usage would fall under the practice of medicine exception and would be outside of FDA's authority?

During the December 12, 1985 meeting, did AcroMed explain to the FDA that it would be submitting two new 510(k) submissions, one for the plates labeled as simple bone plates and one for the screws labeled as simple bone screws?

Does the attached memorandum from Chief, Orthopedic Devices Section, to Karen Stutsman and others, dated April 5, 1990, accurately describe the meeting held between AcroMed and the FDA on December 12, 1985?

Who wrote the memorandum from Chief, Orthopedic Devices Section, to Karen Stutsman and others, dated April 5, 1990?

If you wrote the April 5, 1990 memorandum, did you do so in the regular course of your duties at the FDA?

If you wrote the April 5, 1990 memorandum, when you did so did you know that other FDA employees would rely on the accuracy of the memorandum during their official duties?

Did you write the handwritten sentence that follows the third paragraph on page one of the' April 5, 1990 memorandum?

What does that handwritten sentence say?

Do your initials appear in the margin next to the handwritten sentence?

The April 5, 1990, memorandum indicates that it was sent "to" Karen Stutsman and Leonard Farr "through" Thomas J. Callahan and Carl A. Larson. What does it mean to send a memorandum "through" Carl A. Larson?

Did you send the April 5, 1990 memorandum "through" Carl A. Larson?

Did you send a copy of the April 5. 1990, memorandum to Carl A. Larson?

Did Carl A. Larson ever send you a written response to the April 5, 1990 memorandum?

What, if anything, did Carl A, Larson say in that written response?

Did you ever receive any oral response from Carl A. Larson to the April 5, 1990, memorandum?

What, if anything, did Carl A, Larson say in his oral response to the April 5, 1990 memorandum?

Did Carl A, Larson ever tell you, orally or in writing, that any statement contained in the April 5, 1990 memorandum was inaccurate?

Did AcroMed submit a 510(k) notification for an "AcroMed Nested Bone Plate" (K855224) that was dated January 10, 1986 and received by the FDA on January 17, 1986?

Did you participate in the review process for AcroMed's 510(k) notification for its "Nested Bone Plate"?

When you were participating in the review of AcroMed's 510(k) submission for its "Nested Bone Plate," did you know that the technological characteristics of the "Nested Bone Plate" were essentially identical to the technological characteristics of the "spine plates" that had been included in AcroMed's prior 510(k) notification for a "Variable Screw Placement (VSP) Spinal Plate Fixation System" (K853913)?

Did AcroMed submit a 510(k) notification for an "AcroMed Cancellous Bone Screw" (K860017) that was dated December 30 and 31, 1985 and received by the FDA on January 3, 1986?

Did you participate in the review process for AcroMed's 510(k) notification for its "Cancellous Bone Screw"?

When you were participating in the review of AcroMed's 510(k) submission for its "Cancellous Bone Screw," did you know that the technological characteristics of the "cancellous bone screw" were essentially identical to the technological characteristics of the "cancellous screws" that had been included in AcroMed's prior 510(k) notification for a "Variable Screw Placement (VSP) Spinal Plate Fixation System" (K853913)?

In your opinion, did AcroMed mislead you during the December 12, 1985 meeting about its intention to re-submit 510(k) notifications to obtain clearance of its plates and screws with different labeling?

MEMO

TO: Karen Stutsman, OCS, HFZ-322, Leonard Farr, CIN-DO, HFR-MA440, through Thomas J. Callahan, Branch Chief, Restorative Devices and Carl A. Larson, Div. Director, DSRD, HFZ-410

FROM: Chief, Orthopedic Devices Section, DSRD, HFZ-410

SUBJECT: December 1985 meeting between DSRD staff and representatives of Acromed, Inc., to discuss the not substantially equivalent status of the Variable Screw Placement (VSP) Spinal Fixation System.

DATE: April 5, 1990

In response to proposal for the injunction against Acromed, Inc., I have the following recollections of the December 1985 meeting Acromed Inc., now claims represents FDA sanction of their promotion and commercialization of the VSP system for spinal fixation.

In December 1985 Arthur Steffee, M.D., Edward Wagner, Joseph Radzius, Pam Buckman and 2 other gentleman from Acromed, Inc., whose names escape me, met with Carl A. Larson, Thomas Callahan, and myself. The Acromed, Inc., representatives had come to protest the not substantially equivalent decision that had been given in response to K853913.

The post-Amendments status of transpedicular screw spinal fixation systems was discussed at length. Dr. Steffee was very aggravated at this and was unwilling to accept that a PMA approval was necessary prior to marketing the VSP system for spinal fixation. He and Mr. Radzius badgered the FDA staff at length demanding the right to immediately sell the VSP system for spinal fixation. [Handwritten: They said that [illegible] devices like this are already

out there (in the market) for long bone use and that their product was [illegible] these systems.]

With the meeting at a stalemate I pointed out FDA's long standing policy of evaluating (for not only substantial equivalence but safety and effectiveness) a device based on the labeling submitted for the device and the agreement between the labeling and the device's physical abilities to perform as the labeling claimed. I also pointed out that because of the physical and mechanical similarities between the plates and (the original design) screws of the system to ordinary bone plates and screws these devices, when labeled, indicated and promoted as simple bone screws and plates would, in fact, be substantially equivalent to pre-Amendments devices and could be shipped in interstate commerce. I advised Acromed's representatives that Dr. Steffee, as a publishing researcher, could publish papers in the scientific literature and peer reviewed journals and make scientific presentations before professional society meetings describing his findings from the use of the plates and screws as a system for spinal fixation without violating the FD&C Act. I pointed to the oft stated FDA policy of not regulating the practice of medicine by individual physicians. I said that if individual practitioners, on their own without guidance from labeling or promotion by the manufacturer, chose to use the plates and screws for spinal fixation that would fall under the practice of medicine and outside FDA's authority. I advised Acromed's representatives that any labeling or promotion by the firm of the VSP system for spinal fixation would be a violation of the Act and any presentations by Dr. Steffee would have to be limited to medical society meetings and professional and that these presentations would have to be limited to factual reports of the his findings and not be advertisement or promotion of the system as safe and effective for spinal fixation.

There were a few questions from various Acromed personnel as to the limitations of finding these devices substantially equivalent to

conventional bone plates and the conditions itemized above were restated by myself.

The meeting ended a few minutes later with Acromed announcing that they would be submitting a new 510(k)s, one for the plates and one for the screws.

Department of Health and Human Services
* * *

April 4, 1996

Richard I. Werder, Jr., Esq.
Jones, Day, Reavis & Pogue
North Point
901 Lakeside Avenue
Cleveland, Ohio 44114

Dear Mr. Werder:

The Food and Drug Administration ("FDA") is in receipt of your letter, dated March 1, 1996, requesting the deposition testimony upon written questions of FDA employees Thomas J. Callahan and Daniel S. McGunagle in connection with In re Orthopedic Bone Screw Product Liability Litigation, MDL No. 1014 (E.D. Pa.).

The Agency's regulations prohibit FDA employees from testifying with respect to information acquired in the discharge of their official duties except with the express authorization of the Commissioner of FDA. 21 C.F.R. § 20.1. As Director of the Office of Enforcement, I have been delegated the authority by the Commissioner to review requests for testimony pursuant to Section 20.1. For the reasons set forth below, I must deny your request.

Section 20.1 provides that a request for testimony may only be granted upon a determination that the testimony requested is in the public interest, will promote the objectives of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and will promote the objectives of FDA. However, even when these prerequisites have been satisfied, FDA has discretion to disapprove a request for testimony. Because FDA receives numerous requests for its employees to participate in litigation to which FDA is not a party, it is the policy of the Agency to decline to authorize its employees to testify in their official capacity unless there are compelling circumstances.

Compelling circumstances include cases in which an FDA employee is the only source of the factual information requested, cases in which official records are not available, or cases in which there is an overriding public health interest important enough to justify interrupting the official duties of FDA personnel. This policy has been established to protect the public health by ensuring that FDA employees spend their time pursuing their official duties and not serving as witnesses in private litigation. Our policy is also intended to avoid creating the impression that FDA or one of its employees is taking a partisan position in litigation to which the Agency is not a party.

Based upon information previously provided by your firm to the Agency in connection with the pending litigation and the record presented in your letter of March 1, 1996, there is insufficient information to satisfy the requirements of Section 20.1 or to demonstrate that compelling circumstances exist that would warrant Mr. Callahan and Mr. McGunagle taking government time to testify in the pending litigation.

Although a tremendous amount of public attention has been given to pedicle screw fixation devices, it is not in the public interest for FDA employees to stop performing their official dudes to prepare for and to provide deposition testimony for a civil action between private parties. That is particularly true in this case, in which volumes of FDA documents related to the pedicle screw have already been made available pursuant to the Freedom of Information Act ("FOIA") to both plaintiffs' and defendants' liaison counsel. These documents disclose the nature and basis of FDA action to the extent such disclosure is permitted by law.

Indeed, the written questions submitted with your letter of March 1, 1996 indicate that you already have possession of publicly available documents, such as the April 5, 1990 memorandum by Mr. McGunagle setting forth his recollections of a December 1985 meeting with AcroMed, Inc. representatives. Internal written responses to that memorandum, if any, may already have been

disclosed or may be available to you pursuant to an FOIA request. However, your written questions further suggest that you are seeking information, such as privileged agency communications regarding the December 1985 meeting, that FDA is not required by law to disclose. And, to the extent such communications involved Mr. Larson, you have already had an opportunity to pose such questions to Mr. Larson at two days of depositions taken in connection with the pending litigation.

Based on these facts, I must also conclude that Mr. Callahan and Mr. McGunagle are not the only source of the information you seek. Indeed, the proposed deponents' recollections of a meeting which took place over ten years ago is unlikely to supplement available written records. In addition, certain written questions submitted with your letter of March 1, 1996 are clearly intended to aid in the authentication of the April 5, 1990 memorandum and certain Section 510(k) notifications received by the Agency from AcroMed, Inc. Please be advised that, pursuant to 21 C.F.R. § 20.3, FDA's FOIA office will certify the authenticity of Agency records.

FDA best serves the public interest, not by providing witnesses in private litigation as you request, but rather by enforcement of the FDCA and related statutes. Even were the requested testimony and, more generally, the pedicle screw litigation, considered to serve the public interest, neither promote the principal objectives of the FDCA or the Agency. Indeed, participation by the requested Agency employees in the pending lawsuit would seriously divert those employees from their primary responsibility to review and analyze medical devices in FDA's Center for Devices and Radiological Health and to protect the public health through implementation of the various provisions of the FDCA for which they are responsible. Given the fact that FDA employees serve the public by reviewing a vast number of regulated products, permitting Mr. Callahan and Mr. McGunagle to be deposed in this case would invite requests from many similarly situated private litigants. Responding to all or

even a significant number of these requests would impede the Agency's ability to fulfill its statutory mission.

In addition, the proposed deposition testimony would not promote the objectives of the FDA. The proposed depositions would impede the Agency from implementing its plans and schedules regarding a variety of FDA regulated devices. Thus, diverting these government employees from their assigned duties can only undermine the objectives of the Agency and diminish its ability to enforce the FDCA.

The fact that your request for testimony is limited to written questions does not change my determination in this matter. FDA regards depositions, whether upon written or oral questions, as burdensome to Agency resources. For example, although your list of proposed questions is relatively short, opposing counsel would presumably be entitled to submit unlimited questions for cross-examination, which Mr. Callahan and Mr. McGunagle would be required to answer at deposition.

Accordingly, for the reasons explained above, I am unable to make any of the findings required by 21 C.F.R. § 20.1 or find compelling circumstances to justify the proposed depositions, and I must deny your request to depose Mr. Callahan and Mr. McGunagle. If you have any questions regarding this matter, however, please contact Edward J. Parr, Jr. in FDA's Office of the Chief Counsel, at (301) 827-1143.

Sincerely yours,

/s/
Daniel L. Michels
Director
Office of Enforcement

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

[Caption omitted]

Transcript of 2/6/97 Hearing Before Judge Bechtle

[178] * * *

THE COURT: Who was deceived?

MR. FISHBEIN: The government was deceived, your Honor.

THE COURT: Tell me how.

MR. FISHBEIN: The government was deceived because — let's take Buckman as an example. Well,

[179] let me back up factually.

Buckman in 1994, originally presented the FDA with a 510(k) notification and said, we want clearance to market the VSP spinal fixation system as a spinal system. It is a spinal system. The FDA said, no, no, you can't have that. It is not substantially equivalent. We have questions about the safety and the efficacy, you can't do it.

So Buckman turns around about a year later, and they change the — they cross off the name in the application, they change it to nested bone plates and cancellous bone screws, they present it to the FDA. They say, okay, FDA take a look at this 510(k) notification. This is for bone plates and bone screws to be used in the long bones of the arms and legs. Will you clear it?

Now the FDA maybe efficient in some respects, maybe not, I think we just saw this notification about a year ago or less than that.

THE COURT: At this point, they were not deceived.

MR. FISHBEIN: Right. They wrote to Buckman. In fact, they said, Buckman, would you please tell us what is going on here? What do you intend to use this product for? Buckman writes back

[180] in a letter of January 10, 1986.

The proposed indications for use of the AcroMed device are the same general indications proposed for the AO system of plates, more specifically for purpose of this 510(k), the AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and the lower extremity, and such other flat bones as in the fractured pelvis that may from time to time require stabilization with contourable, metallic, non-compressing plates. They said this is a long bone fixation device. This is how we intend to use it. This is the kind of device that you should approve, FDA. The FDA, based on that representation, said, we know they are not appropriate as a spine device.

THE COURT: What?

MR. FISHBEIN: You have 510 (k) clearance to market this device.

THE COURT: For what?

MR. FISHBEIN: They say for the proposed indications. Long bone.

THE COURT: FDA was not deceived.

MR. FISHBEIN: In my view, your Honor, the FDA was deceived because here is, I think, the

[181] central point, unlike other devices that have multiple indications and can be used in multiple ways, the VSP device didn't. It wasn't a long bone use. It wasn't a long bone — I'm sorry. It was not a long bone fixation device. It couldn't be used as a long bone fixation device, AcroMed didn't intend it that way, Buckman didn't intend it that way. Nobody intended it that way. It was never used that way. It couldn't be used that way and it was just a lie so they could get this clearance then proceed with the second part of their plan, which was to go out in the market and get doctors to say, you can use it for, in our own medical judgment, we think you can use it as a spinal fixation device. In fact, our discovery revealed it was never used.

[182] THE COURT: How was the FDA compromised?

MR. FISHBEIN: The FDA was compromised.

THE COURT: They didn't believe Buckman.

MR. FISHBEIN: When they got the second —

THE COURT: It mean it would seem to me it's likely they were not fooled by Buckman because they said you offered it for this, you can use it for this. They may have said in their private quarters, "We think this spinal key really wants to use the long bone thing for the spine. We believe it's appropriate for long bone and we'll limit it to that."

Tell me about the fraud.

MR. FISHBEIN: The fraud, your Honor, is that that was not a truthful statement. If Buckman had made a truthful statement, the FDA would never have issued the clearance and the device could not have been placed in distribution.

THE COURT: Who said they never would have issued for long bone? Who said the FDA, if they had known that doctors might use this for pedicle that they would not issue it for long bone.

MR. FISHBEIN: The question is not the limitation for long bone. The question is, the FDA depends on truthful representations and because Buckman said long bone, the FDA granted the clearance which was the legal ticket in the marketplace.

Our position is, if Buckman had told them the truth, [183] the truth being that this device is not intended for long bone use, then the FDA as evidenced by their prior conduct could not legally have cleared it. It would never have had a legal ticket into the marketplace and all of the subsequent promotional shenanigans could not have taken place.

THE COURT: All right, let's assume for the moment that FDA was misled and they approved it for the described uses in the application, which was not spinal fixation.

MR. FISHBEIN: Correct.

THE COURT: So they went out into the market place and promoted it for spinal fixation.

MR. FISHBEIN: Correct.

THE COURT: What does that have to do with anything FDA did?

MR. FISHBEIN: Because —

THE COURT: How did that program make any difference? What if FDA said, "We won't approve this for long bone"?

MR. FISHBEIN: Then the device would not have come into the market. The FDA is the gatekeeper. The product — if it does not have a 510(k) clearance, it's subject to seizure. It can't be placed in commerce for any purpose, at all.

So this became the legal ticket by which it was placed into the marketplace and it's the but for the reason why the [184] product got into the marketplace, which was a scheme hatched between Buckman and AcroMed to promote it for a so-called "off label use." * * * *